

# Public Case Detail

Cases Count: 393

**Case Number : 231515**

**Data Entry Date :** 03/08/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 28/03/1974

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** White blood cell count and neutrophil counts were within normal ranges for the treatment period.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient developed myocarditis.	

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 05/06/2007	<b>Stopped :</b> 27/06/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 231531**

**Data Entry Date :** 06/08/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 28/06/2007

**Age :**

**DOB :** 31/10/1961

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** White blood cell (WBC) and neutrophil counts (NC) had been normal for the treatment period prior to this event.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced neutropenia and leucopenia.	Ceased clopine.
Leukopenia			

## Medicine details :

**CLOPINE (Suspected)**

**Reason :**

Tablet

200 Milligram

Daily

Oral

**Batch :**

**Started :** 17/11/2003

**Stopped :** 29/06/2007

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		31/05/2007	11.30	
White blood cells		25/06/2007	3.60	
White blood cells		28/06/2007	2.70	
White blood cells		30/06/2007	4.50	
White blood cells		05/07/2008	7.60	
Neutrophils		31/05/2007	5.70	
Neutrophils		25/06/2007	1.80	
Neutrophils		28/06/2007	0.80	
Neutrophils		30/06/2007	1.80	
Neutrophils		05/07/2008	5.30	

## Case Number : 231546

Data Entry Date : 06/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 25/07/1975

Outcome :

Causality : Causality probable

Unknown

**Information:** Patient commenced treatment with clozapine on 2/08/2004 for treatment of schizophrenia and switched to Clopine (clozapine) on 7/11/2006. Patient has been taking Clopine PO 900mg daily since commencing Clopine treatment.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Ejection fraction decreased		Patient experienced reduced left ventricular function, chest pain, shortness of breath, sinus tachycardia, supraventricular ectopic beats, elevated creatine kinase and elevated triglycerides whilst on Clopine.	Clopine treatment is continuing pending advice from cardiologist.
Blood creatine phosphokinase increased			
Blood triglycerides increased			
Chest pain			
Dyspnoea			
Sinus tachycardia			
Supraventricular extrasystoles			

### Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	900 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 07/11/2006	<b>Stopped :</b> 09/08/2007	Contin

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				ECHO was normal pre-clozapine commencement (with the exception of sinus tachycardia. 12/08/2004 ECHO sinus tachycardia (130BPM). 30/04/2007 ECHO sinus tachycardia 900mg 30/04/2007 ECHO ejection fraction 46% 900mg
Creatine phosphokinase		18/06/2007	290	
Triglyceride		18/06/2007	6.5	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography				18/01/2006 ECG Supraventricular ectopic 700mg.

## Case Number : 231547

Data Entry Date : 06/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 21/06/2007

Age :

DOB : 22/09/1971

Outcome : 02/07/2007

Causality : Causality probable

Recovered

**Information:** The patient commenced treatment with Clopine on 6/06/2007 and was titrated up to po 225mg daily. In June 2007, the patient experienced the event.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced myocarditis. Tachycardia (140), Hypotension (100/60) and elevated creatine kinase (67) and toponin 1 increased (0.45)	Clopine ceased.
Pyrexia		Temp of 38.5 degrees C	
Blood creatine phosphokinase increased			
Hypotension			
Tachycardia			
Troponin I increased			

### Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
Tablet	200 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 06/06/2007 <b>Stopped :</b> 21/06/2007 0
<b>SODIUM VALPROATE (Other drug)</b>	<b>Reason :</b>
	1.4 Gram
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>VENLAFAXINE HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b> Depression
	150 Milligram Daily
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells				White cell counts were within the normal range throughout treatment.
Neutrophils				Neutrophil counts were within the normal ranges throughout treatment.

## Case Number : 231548

Data Entry Date : 06/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 60.5

Onset Date : 22/06/2007

Age :

DOB : 02/05/1979

Outcome : 27/06/2007

Causality : Causality possible

Recovered

Information: Positive dechallenge.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation	Patient experienced severe tachycardia, moderate fever, headache, myalgia.	Clopine discontinued.
Pyrexia	Caused or prolonged inpatient hospitalisation		

### Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	200 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 12/06/2007 <b>Stopped :</b> 23/06/2007
<b>SODIUM VALPROATE (Other drug)</b>	<b>Reason :</b>
	1 Gram
<b>Batch :</b>	<b>Started :</b> 12/04/2007 <b>Stopped :</b>
<b>ZUCLOPENTHIXOL DECANOATE (Other drug)</b>	<b>Reason :</b>
Injection	200 Milligram Intramuscular
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				22/06/2007 Cardiac rate 136bpm. 23/06/2007 Cardiac rate 144 bpm.
Blood pressure		22/06/2007	120/80	
Blood pressure		23/06/2007	110/60	
Temperature		22/06/2007	38	
Temperature		23/06/2007	38	

# Public Case Detail

Cases Count: 393

**Case Number : 231549**

**Data Entry Date :** 06/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 30/06/2007

**Age :**

**DOB :** 08/11/1953

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Patient experienced neuroleptic malignant syndrome whilst on Clozaril treatment.	Clozaril put on hold.

**Medicine details :**

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	250 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 13/06/2007	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 231573**

**Data Entry Date :** 07/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 29/10/1969

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		The patient experienced myocarditis	ceased treatment

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	12.5 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 18/06/2007	<b>Stopped :</b>	02/07/2007



## Case Number : 231577

**Data Entry Date :** 07/08/2007

**Gender :** F

**Hospitalisation :** Required a specialist consultation

**Weight (kg) :** 0

**Onset Date :** 03/07/2007

**Age :**

**DOB :** 25/09/1943

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** Patient had experienced seizures in 1998-1999. Dose of Clozaril had been reduced and valproate dose increased.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient experienced seizures.	Clozaril ceased and recommenced at a lower dose of 200mg/daily form 350mg/daily.
Drug level below therapeutic	Caused or prolonged inpatient hospitalisation		
Leukopenia	Caused or prolonged inpatient hospitalisation		

### Medicine details :

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 23/11/2001	<b>L TERM</b>	<b>Stopped :</b> 19/09/2007 0
<b>SODIUM VALPROATE (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level		31/12/2006	136	Low valproate levels
Serum drug level		22/03/2007	342	Low valproate levels
Serum drug level		26/04/2007	284	Low valproate levels
White blood cells		17/09/2007	3.30	
White blood cells		19/09/2007	2.70	
White blood cells		20/09/2007	3.20	
White blood cells		21/09/2007	3.20	
White blood cells		24/09/2007	4.30	
White blood cells		25/09/2007	3.40	
White blood cells		28/09/2007	3.70	
White blood cells		01/10/2007	3.30	

# Public Case Detail

Cases Count: 393

**Case Number : 231626**

Data Entry Date : 08/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/07/2007

Age :

DOB : 11/08/1971

Outcome :

Causality : Causality possible

Recovered

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis	ceased treatment with Clopine
Pyrexia			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>			
Tablet	175 Milligram	Daily	Oral
Batch :	Started : 21/06/2007	Stopped : 04/07/2007	0
<b>GLICLAZIDE (Other drug)</b>			
Batch :	Started :	Stopped :	
<b>METFORMIN HYDROCHLORIDE (Other drug)</b>			
Batch :	Started :	Stopped :	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Troponin				Troponin I increased
Creatine phosphokinase				Creatine kinase increased

# Public Case Detail

Cases Count: 393

**Case Number : 231628**

**Data Entry Date :** 08/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 20/12/1966

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Ventricular dysfunction		Ventricular dysfunction	Clozaril was ceased

**Medicine details :**

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>
Tablet	75 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 29/01/2001 <b>Stopped :</b> 03/07/2007

# Public Case Detail

Cases Count: 393

**Case Number : 231691**

**Data Entry Date :** 08/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 05/06/2007

**Age :**

**Outcome :** 13/06/2007

**DOB :** 28/05/1967

Recovered

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Intestinal obstruction		Patient experienced a bowel obstruction.	Temporary discontinuation of Clozaril

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Schizophrenia	
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 07/11/1997	<b>Stopped :</b> 12/06/2007	0

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Abdomen X-ray				Abdominal x-ray 6/6/07: Early or partial small bowel obstruction in meddle small bowel.

## Case Number : 231695

Data Entry Date : 09/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/05/2007

Age :

DOB : 17/01/1933

Outcome :

Causality : Causality certain

Not yet recovered

**Information:** Rechallenged with Clozaril 300mg daily with subsequent drop in conscious state. That patient also had a history of alcohol abuse. PMHx Diabetes mellitus, Transient ischaemic attack and Cerebrovascular accident.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Dysarthria	Caused or prolonged inpatient hospitalisation	Patient was hospitalised after a physical decline in function for three weeks, increasing difficulty to walk, speech increasingly incomprehensible and difficulty in swallowing, 2 weeks of jerky limb movements. The patient was drowsy and incontinent, a diagnosis of seizures secondary to clozapine/lithium toxicity was made.	Lithium ceased, clozaril temporarily ceased, rechallenged, dosage reduced to 150mg daily. Commenced valproate.
Convulsion	Caused or prolonged inpatient hospitalisation		
Depressed level of consciousness	Caused or prolonged inpatient hospitalisation		
Dyskinesia	Caused or prolonged inpatient hospitalisation		
Dysphagia	Caused or prolonged inpatient hospitalisation		
Incontinence	Caused or prolonged inpatient hospitalisation		
Renal impairment	Caused or prolonged inpatient hospitalisation		
Sedation	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		
Therapeutic agent toxicity	Caused or prolonged inpatient hospitalisation		

## Medicine details :

### CLOZAPINE (Suspected)

Reason : Unspecified schizophrenia

Tablet 300 Milligram Daily Oral

Batch : Started : 17/02/2000 Stopped : 30/05/2007 0

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### LITHIUM CARBONATE (Other drug)

Reason :

375 Milligram Alternate days

Batch : Started : Stopped : 30/05/2007 0

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## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level				30 May 2007: Clozapine level = 435, Lithium level = 0.84 (0.60-1.00). Estimated Glomerular Filtration Rate (GFR): 42 mL/min/173m2.
Sodium		30/05/2007	156	
Creatinine		30/05/2007	116	
Electroencephalograph				1 June 2007: EEG showed frontotemporal epileptiform activity (left>right).

# Public Case Detail

Cases Count: 393

**Case Number : 231706**

**Data Entry Date :** 09/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 01/07/2007

**Age :**

**DOB :** 05/02/1977

**Outcome :** 01/07/2007

**Causality :** Causality possible

Death

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Death	Death	Death Unexplained	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 25/01/2007	<b>Stopped :</b> 01/07/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 231739**

**Data Entry Date :** 09/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 130

**Onset Date :** 02/03/2007

**Age :**

**DOB :** 07/08/2007

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** Smoker 15 cig/day.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Ejection fraction decreased	Life threatening	On commencement of Clozapine therapy echo showed left ventricular ejection decreased (from Echo in May 2005) . Other side effects included hypersalivation and increased urinary micturition, as well as weight gain. Grade b heart failure.	Initiation of Beta Blocker ACE-I therapy
Cardiac failure	Life threatening		
Polyuria	Life threatening		
Salivary hypersecretion	Life threatening		
Weight increased	Life threatening		

## Medicine details :

**CLOZAPINE (Suspected)**

**Reason :** Unspecified schizophrenia

Tablet

700 Milligram

Daily

Oral

**Batch :**

**Started :**

**Stopped :** 28/03/2007



## Case Number : 231798

**Data Entry Date :** 10/08/2007  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 06/07/2007  
**Outcome :**  
 Not yet recovered

**Gender :** M  
**Weight (kg) :** 78  
**Age :**  
**DOB :** 26/02/1973  
**Causality :** Causality possible

**Information:** Half brother has IDDM

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Diabetic ketoacidosis	Life threatening	Patient experienced diabetic ketoacidosis - flu-like symptoms, abdominal pains, productive cough, shortness of breath, pale, lethargic, confusion.	
Abdominal pain	Life threatening		
Confusional state	Life threatening		
Dyspnoea	Life threatening		
Influenza like illness	Life threatening		
Lethargy	Life threatening		
Pallor	Life threatening		
Productive cough	Life threatening		

### Medicine details :

<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	250 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	L TERM	<b>Stopped :</b> 11/07/2007

# Public Case Detail

Cases Count: 393

**Case Number : 231833**

**Data Entry Date :** 10/08/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 28/06/1937

**Outcome :**

**Causality :** Causality possible

Unrelated death

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Death	Death	Death unexplained.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	225 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 14/02/2007	<b>Stopped :</b> 31/07/2007	

## Case Number : 231847

Data Entry Date : 13/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 10/05/2007

Age :

DOB : 16/04/1973

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Epilepsy		Patient was commenced on Clozaril on 24 Feb 2005. In June 2007 the patient complained of blackouts. An EEG was performed and showed clear epileptic features.	Patient commenced antiepileptic Epilim (sodium valproate). Clozaril dose was slowly reduced.
Electroencephalogram abnormal			
Loss of consciousness			

#### Medicine details :

CLOZARIL (Suspected)	Reason :
Tablet	175 Milligram Daily Oral
Batch :	Started : 24/02/2005 Stopped :

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electroencephalograph				EEG showed clear epileptic features.

# Public Case Detail

Cases Count: 393

**Case Number : 231849**

**Data Entry Date :** 13/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 08/07/2007

**Age :**

**DOB :** 06/12/1952

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Circulatory collapse	Caused or prolonged inpatient hospitalisation	Patient was taking Clozaril since 19 Nov 1998. On 8 July 2007 the patient collapsed and was hospitalised. Clozaril treatment remained ongoing.	Aspirin and Citalopram
Atrial fibrillation	Caused or prolonged inpatient hospitalisation		
Convulsion	Caused or prolonged inpatient hospitalisation		
Drug level increased	Caused or prolonged inpatient hospitalisation		
Troponin I increased	Caused or prolonged inpatient hospitalisation		

**Medicine details :**

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	25 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 19/11/1998 <b>Stopped :</b>
<b>CIPRAMIL (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Troponin	<0.08	12/12/2006	0.01	
Troponin	<0.08	08/07/2007	0.16	
Troponin	<0.08	12/07/2007	0.04	
Serum drug level	350 - 450	21/08/2007	692	Clozapine levels in 2002 were 254.

# Public Case Detail

Cases Count: 393

**Case Number : 231852**

**Data Entry Date :** 13/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 06/07/2007

**Age :**

**DOB :** 21/08/1985

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient was taking Clozril since 15 June 2007. On 6 July 2007 the patient was diagnosed with myocarditis.	Ceased Clozaril
Blood creatine phosphokinase increased			
Pyrexia			
Tachycardia			
Troponin I increased			

**Medicine details :**

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Othr&unspec metabolic diseases		
Tablet	12.5 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/06/2007	<b>Stopped :</b> 06/07/2007	0

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		05/07/2007	70	
Creatine phosphokinase		09/07/2007	81	
Creatine phosphokinase		13/07/2007	90	
Troponin		05/07/2007	0.15	
Troponin		09/07/2007	0.25	
Troponin		13/07/2007	<0.10	

## Case Number : 231854

Data Entry Date : 13/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 12/06/2007

Age :

DOB : 31/05/1970

Outcome :

Causality : Causality possible

Unknown

**Information:** The patient had normal Troponin results.  
It was not confirmed if Clozaril was ceased.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Ventricular dysfunction		Patient was on Clozaril morning and evening. Patient had regular Doppler echocardiography which showed deterioration of left and right ventricular function. Creatine Kinase increased (CK 501). Patient consulted a cardiologist who suggested Clozaril should be ceased. It was not confirmed if Clozaril was ceased. Olanzapine and Valproate was commenced.	
Blood creatine phosphokinase increased			

### Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	500 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started : 22/06/1999</b>	<b>Stopped :</b>	

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		28/06/2007	501	
Creatine phosphokinase		04/07/2007	189	
Creatine phosphokinase		07/07/2007	228	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography				<p>09 Dec 2005 Doppler echocardiography: 1. Normal left ventricular size and function 2. No significant valvular abnormalities.</p> <p>28 Dec 2005 Doppler Exhocardiography: 1. Normal left ventricular cavity size and borderline normal systolic function 2. No significant valvular abnormalities.</p> <p>12 Jun 2007 Doppler Echocardiography: Normal left ventricular size with mildly impaired systolic function. 2. Upper normal right ventricular dimensions with mildly impaired systolic function. 3. No significant valvular abnormalities 4. Some deterioration of left and right ventricular function.</p>

## Case Number : 231863

Data Entry Date : 13/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 02/07/2007

Age :

DOB : 30/09/1941

Outcome :

Causality : Causality possible

Recovered

### Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Left ventricular failure	Caused or prolonged inpatient hospitalisation	Non-specific intraventricular conduction block. Left ventricular failure.	

Medicine details :			
<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>Aripiprazole (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>ATORVASTATIN (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>Bisoprolol Fumarate (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>FRUSEMIDE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>TRANDOLAPRIL (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>VENTOLIN (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	



# Public Case Detail

Cases Count: 393

**Case Number : 231866**

**Data Entry Date :** 13/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 24/06/2007

**Age :**

**DOB :** 26/11/1981

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** History of Alcoholism and Renal impairment. The physician stated that the high urea and high creatinine were also pre-existing conditions. Recovered from the increased c-reactive protein and increased blood glucose.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Patient experienced pyrexia, c-reactive protein increased, blood creatinine increased and blood glucose increased.	
Abdominal pain			
Blood creatinine increased			
Blood glucose increased			
C-reactive protein increased			
Cough			
Malaise			
Nasal congestion			

## Medicine details :

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	200 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 22/06/2007 <b>Stopped :</b> Ongoing.
<b>LIPITOR (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>LORAZEPAM (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>THIAMINE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatinine	<10			CRP: 229, 252, 43 and on 17 July CPR: 4.
Serum glucose	3.8 - 5.5	02/07/2007	8.8	
Serum glucose	3.8 - 5.5	10/07/2007	5	



# Public Case Detail

Cases Count: 393

**Case Number : 231877**

**Data Entry Date :** 13/08/2007  
**Hospitalisation :** Admitted to hospital  
**Onset Date :**  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 13/03/1948  
**Causality :** Causality possible

**Information:** Patient has had a previous history of bowel obstruction.

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Intestinal obstruction	Caused or prolonged inpatient hospitalisation	Patient had bowel obstruction whilst on Clopine therapy.	Required surgical intervention. Clopine ceased for 3 days, but is not continuing.

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 18/05/2006	<b>Stopped :</b>	

## Case Number : 231894

Data Entry Date : 13/08/2007

Gender : F

Hospitalisation : Treated in Accident/Emergency Depar

Weight (kg) : 0

Onset Date : 30/06/2007

Age :

Outcome : 03/07/2007

DOB : 11/12/1982

Recovered

Causality : Causality probable

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Overdose	Caused or prolonged inpatient hospitalisation	On the night of 01/07/07, patient overdosed on Clopine by taking 1050mg oral instead of 200mg oral and experienced drowsiness and chest tightness.	Taken to emergency department for monitoring.
Chest discomfort	Caused or prolonged inpatient hospitalisation		
Somnolence	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	1 Gram	1 time	Oral
Batch :	Started : 30/06/2007	Stopped :	0

# Public Case Detail

Cases Count: 393

**Case Number : 231940**

**Data Entry Date :** 14/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 02/07/2007

**Age :** 37Y

**Outcome :**

**DOB :**

Not yet recovered

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis. Creatine kinase increased.	Cessation of Clozapine. Commenced aspirin, bisoprolol and paracetamol
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	175 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 18/06/2007	<b>Stopped :</b> 02/07/2007	
<b>SOMAC (Other drug)</b>		<b>Reason :</b>	
Tablet	40 Milligram		Oral
<b>Batch :</b>	<b>Started :</b> 12/06/2007	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Other data				LVEF 312
Creatine phosphokinase		02/07/2007	463	
Creatine phosphokinase		03/07/2007	290	
Troponin		02/07/2007	3.06	
Troponin		03/07/2007	2.99	
C-Reactive Protein		02/07/2007	265.7	

# Public Case Detail

Cases Count: 393

**Case Number : 231943**

**Data Entry Date :** 14/08/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 04/01/1975

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis/pericarditis	
Pericarditis	Caused or prolonged inpatient hospitalisation		

**Medicine details :**

<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	75 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 05/07/2007	<b>Stopped :</b>	

## Case Number : 232018

Data Entry Date : 15/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 21/05/2007

Age :

DOB : 24/06/1967

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiac enzymes increased		Raised cardiac enzymes. Shortness of breath. Central chest tightness.	Clozaril ceased
Blood creatine phosphokinase increased			
Chest discomfort			
Dyspnoea			
Monocyte count increased			
Treatment noncompliance			
Troponin I increased			

#### Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason : Unspecified schizophrenia</b>	
Tablet	75 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started : 25/11/2005</b>	<b>Stopped : 03/02/2007</b>	

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		05/07/2007	328	
Creatine phosphokinase		16/07/2007	108	
Troponin		05/07/2007	0.05	
Troponin		16/07/2007	0.03	
Monocytes	(02.8)	21/05/2007	0.9	
Monocytes	(02.8)	16/07/2007	0.8	
Electrocardiography				No acute changes.
Other data				12 Jul 2007 Transthoracic echocardiogram:normal.

# Public Case Detail

Cases Count: 393

**Case Number : 232059**

**Data Entry Date :** 16/08/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 09/07/2007

**Age :**

**DOB :** 25/09/1974

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Neutrophilia		Patient experienced neutrophilia. Leukocytosis.	
Leukocytosis			

<b>Medicine details :</b>			
CLOZARIL (Suspected)	Reason :		
Tablet	150 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 22/08/2006	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		09/07/2007	32.6	
Neutrophils		09/07/2007	27.10	





# Public Case Detail

Cases Count: 393

**Case Number : 232060**

**Data Entry Date :** 16/08/2007

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Gender :** M

**Weight (kg) :** 0

**Age :** 29Y

**DOB :**

**Causality :** Causality possible

## Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Chest pain		Chest pain. Troponin I increased. Blood creatine phosphokinase increased. Blood creatine phosphokinase MB increased.	
Blood creatine phosphokinase MB increased			
Blood creatine phosphokinase increased			
Troponin I increased			

### Medicine details :

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>	
Tablet	400 Milligram Daily Oral	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 232099**

**Data Entry Date :** 16/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 01/04/2007

**Age :**

**Outcome :** 12/04/2007

**DOB :** 14/10/1980

Recovered

**Causality :** Causality probable

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Tachycardia	Incapacity/disability	Patient experienced tachycardia. Unresponsive to beta-blockers and worsened by anxiety.	Patient ceased Clopine

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	650 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 13/09/2004	<b>Stopped :</b> 11/04/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 232149**

**Data Entry Date :** 17/08/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/07/2007

**Age :**

**DOB :** 04/01/1975

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Patient experienced Myocarditis in July after treatment with Clopine.	Ceased treatment.

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	250 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 05/07/2007	<b>Stopped :</b> 23/07/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 232150**

**Data Entry Date :** 17/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 14/10/1977

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis	Ceased treatment

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>	
Tablet	350 Milligram	Daily
<b>Batch :</b>	<b>Started :</b> 28/06/2007	<b>Stopped :</b> 23/07/2007
		Oral

## Case Number : 232152

Data Entry Date : 17/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 18/05/2007

Age :

DOB : 21/07/1970

Outcome :

Causality : Causality possible

Recovered

Information: History of epilepsy and fits.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Pleural effusion	Caused or prolonged inpatient hospitalisation	Eosinophilic pleural effusion, eosinophilia and neutropenia.	Clozaril discontinued. Treated with antibiotics and received an aspiration of the effusion.
Eosinophilia	Caused or prolonged inpatient hospitalisation		
Neutropenia	Caused or prolonged inpatient hospitalisation		

### Medicine details :

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	200 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 04/05/2007 <b>Stopped :</b> 29/05/2007
<b>LAMICTAL (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>QUETIAPINE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>SODIUM VALPROATE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>VENLAFAXINE HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 232178**

**Data Entry Date :** 17/08/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/07/2007

**Age :**

**DOB :** 09/05/1961

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Depressed mood		Patient experienced nausea, some lethargy and depressed mood.	
Lethargy			
Nausea			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 25/03/1996	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 232230**

Data Entry Date : 20/08/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 26/06/2007

Age :

Outcome : 26/06/2007

DOB : 20/02/1976

Death

Causality : Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Sudden death	Death	Patient experienced sudden death.	

**Medicine details :**

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	600 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 26/05/1997 <b>Stopped :</b> 26/06/2007
<b>DIAZEPAM (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>DIAZEPAM (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>SODIUM VALPROATE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>SODIUM VALPROATE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

# Public Case Detail

Cases Count: 393

## Case Number : 232258

**Data Entry Date :** 20/08/2007  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 22/07/2007  
**Outcome :**  
 Unknown

**Gender :** F  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 25/02/1942  
**Causality :** Causality possible

### Information:

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Convulsion	Caused or prolonged inpatient hospitalisation	Patient experienced a seizure, lower respiratory tract infection and pyrexia.	
Lower respiratory tract infection	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	500 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 22/08/1996	L TERM	<b>Stopped :</b> Ongoing.

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
White blood cells		04/06/2007	15.9 x 10 <sup>9</sup> /L	
White blood cells		29/06/2007	12.3 x 10 <sup>9</sup> /L	
Neutrophils		04/06/2007	12.0 x 10 <sup>9</sup> /L	
Neutrophils		29/06/2007	12.30 x 10 <sup>9</sup> /L	



## Case Number : 232272

**Data Entry Date :** 20/08/2007  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 02/06/2007  
**Outcome :**  
 Not yet recovered

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 19/01/1980  
**Causality :** Causality possible

### Information:

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Tachycardia	Caused or prolonged inpatient hospitalisation	Patient experienced tachycardia, raised blood creatine, troponin increased, flu like symptoms, myalgia and fever.	
Blood creatine increased	Caused or prolonged inpatient hospitalisation		
Influenza like illness	Caused or prolonged inpatient hospitalisation		
Myalgia	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOZAPINE (Suspected)</b>	<b>Reason :</b> Other myocardial insufficiency		
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 16/05/2007	<b>Stopped :</b> 03/06/2007	0

# Public Case Detail

Cases Count: 393

**Case Number : 232306**

**Data Entry Date :** 21/08/2007  
**Hospitalisation :** Admitted to hospital  
**Onset Date :**  
**Outcome :**  
 Recovered

**Gender :** F  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 08/08/1978  
**Causality :** Causality probable

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Urinary incontinence	Caused or prolonged inpatient hospitalisation	Urinary incontinence (nocturnal). Patient has been tried on Oxybutynin and Desmopressin nasal spray without much effect. Patient attempted suicide as she felt she was disgusting upon recurrence of incontinence. Threatens to suicide if maintained on Clozapine.	Oxybutynin and Desmopressin. Cessation of Clozapine.

<b>Medicine details :</b>			
<b>CLOZAPINE (Suspected)</b>			
Tablet	500 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 06/12/2006	<b>Stopped :</b> 01/08/2007	
<b>Ciclesonide (Other drug)</b>			
Inhalation	80 Microgram		Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>OMEPRAZOLE (Other drug)</b>			
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>SALBUTAMOL (Other drug)</b>			
<b>Batch :</b>	<b>Started :</b>		Inhalation
		<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 232364**

**Data Entry Date :** 22/08/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 43Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:** the reporting healthcare practitioner suspected that the event may be due to lithium overdose but was unsure.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Renal failure acute		Patient experienced acute renal failure.	

## Medicine details :

**CLOZAPINE (Suspected)**

**Reason :**

Tablet

200 Milligram Daily

Oral

**Batch :**

**Started :**

**Stopped :**

**LITHIUM CARBONATE (Suspected)**

**Reason :**

**Batch :**

**Started :**

**Stopped :**

# Public Case Detail

Cases Count: 393

**Case Number : 232432**

**Data Entry Date :** 23/08/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 16/12/1986

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** white blood cell counts and neutrophil counts were within normal ranges for the treatment period.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced seizures while being treated with Clopine.	Ceased treatment

## Medicine details :

<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	650 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 13/11/2006	<b>Stopped :</b>	0

# Public Case Detail

Cases Count: 393

**Case Number : 232440**

**Data Entry Date :** 23/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 07/09/1977

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** WCC and NC have been within the normal ranges throughout treatment.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced seizures while being treated with Clopine.	dose reduction from 700mg to 650mg

## Medicine details :

CLOZAPINE (Suspected)

**Reason :**

Tablet

700 Milligram

Daily

Oral

**Batch :**

**Started :** 11/01/2005

**Stopped :**

0

## Case Number : 232463

Data Entry Date : 24/08/2007

Hospitalisation :

Onset Date : 05/08/2007

Outcome :

Unknown

Gender : F

Weight (kg) : 0

Age :

DOB : 21/07/1986

Causality : Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced myocarditis, cardiomyopathy and neutropenia while being treated with Clozaril..	Ceased treatment.
Cardiomyopathy			
Neutropenia			

#### Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	50 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 30/06/2007	<b>Stopped :</b>	05/08/2007

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		05/08/2007	0.90 x 10 <sup>9</sup> /L	
Neutrophils		06/08/2007	1.1 x 10 <sup>9</sup> /L	

# Public Case Detail

Cases Count: 393

**Case Number : 232506**

**Data Entry Date :** 27/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/06/2007

**Age :**

**DOB :** 15/04/1966

**Outcome :**

**Causality :** Causality probable

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
White blood cell count decreased	Death	Patient experienced a red range blood count and neutrophil count decreased.	Clozaril ceased.
Neutrophil count decreased	Death		

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	75 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 11/12/2006	<b>Stopped :</b> 27/06/2007	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
White blood cells		26/06/2007	3.80 x 10 <sup>9</sup> /L	
Neutrophils		26/06/2007	1.40 x 10 <sup>9</sup> /L	

## Case Number : 232507

Data Entry Date : 27/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 58.5

Onset Date : 12/07/2007

Age :

DOB : 21/08/1978

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Ventricular hypertrophy		Patient experienced mild septal hypertrophy, mild QTc prolongation and sinus tachycardia whilst on Clopin therapy.	
Electrocardiogram QT prolonged			
Sinus tachycardia			

#### Medicine details :

##### CLOPINE (Suspected)

Reason :

Tablet 700 Milligram Daily Oral

Batch : Started : 02/05/2006 Stopped :

##### CHLORPROMAZINE HYDROCHLORIDE (Other drug)

Reason :

Batch : Started : Stopped :

##### ZOPICLONE (Other drug)

Reason :

Batch : Started : Stopped :

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram		12/07/2007	Mild septal hypertrophy	Patient reported to be asymptomatic.
Echocardiogram		12/07/2007	Sinus tachycardia (115-120bpm)	Patient reported to be asymptomatic.
Echocardiogram		27/07/2007	Mild QTc prolongation (452)	Patient reported to be asymptomatic.



# Public Case Detail

Cases Count: 393

**Case Number : 232511**

**Data Entry Date :** 27/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 21/10/1939

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** White blood cell count and neutrophil counts were within normal ranges for the treatment period.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Whilst on Clopine therapy, patient developed myocarditis.	Clopine ceased.

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	175 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 30/08/2005	<b>Stopped :</b>	10/07/2007

# Public Case Detail

Cases Count: 393

**Case Number : 232530**

**Data Entry Date :** 27/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 26/07/2007

**Age :**

**DOB :** 10/11/1968

**Outcome :** 26/07/2007

**Causality :** Causality possible

Death

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Death	Death	Patient commenced treatment with Clopine on 22/05/06 and was titrated to a maximum dose of 600mg daily, which the patient was taking at the time of death. Cause of death was unknown at the time of reporting.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	600 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 22/05/2006	<b>Stopped :</b> 26/07/2007	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Other data				White blood cell count and neutrophil counts were within normal ranges for the treatment period, with exception of a few slightly raised counts on two testing occasions.

# Public Case Detail

Cases Count: 393

**Case Number : 232611**

**Data Entry Date :** 28/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 27/01/1974

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** White blood cell counts and neutrophil counts were within normal ranges for the treatment period.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient developed myocarditis.	Clopine ceased.

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	225 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 24/07/2007	<b>Stopped :</b> 07/08/2007	

# Public Case Detail

Cases Count: 393

## Case Number : 232613

**Data Entry Date :** 28/08/2007  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 15/07/2007  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 10/05/1954  
**Causality :** Causality possible

### Information:

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Intestinal obstruction	Caused or prolonged inpatient hospitalisation	Patient experienced a bowel obstruction and white blood cell counts and neutrophil counts were high on several test occasions throughout the duration of treatment, and the patient had also experienced neutropenia in 2004.	Patient required surgery.
Neutropenia	Caused or prolonged inpatient hospitalisation		
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	700 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 02/10/2002	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		28/05/2007	17.80 x10 <sup>9</sup> /L	700mg
Neutrophils		28/05/2007	15.00 x10 <sup>9</sup> /L	700mg

# Public Case Detail

Cases Count: 393

**Case Number : 232642**

**Data Entry Date :** 28/08/2007

**Gender :** F

**Hospitalisation :** Required a visit to the doctor

**Weight (kg) :** 0

**Onset Date :** 18/07/2007

**Age :**

**DOB :** 30/01/1977

**Outcome :** 18/07/2007

**Causality :** Causality possible

Unrelated death

**Information:** History of obesity.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Sudden death	Death	Patient died a sudden death.	

## Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 17/07/2007	<b>Stopped :</b> 18/07/2007	
<b>SEROQUEL (Suspected)</b>		<b>Reason :</b>	
Tablet			Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 232660**

**Data Entry Date :** 29/08/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 24/08/1961

**Outcome :**

**Causality :** Causality possible

Unrelated death

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Death	Death	Death unexplained.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	475 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 06/03/2004	<b>Stopped :</b> 27/07/2007	

## Case Number : 232723

Data Entry Date : 29/08/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 30/11/1984

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Heart rate increased		Patient experienced an increased heart rate of 145 beats per minute. White blood cell count decreased to 3.4. Neutrophil count decreased to 1.4.	Clozaril ceased.
Neutropenia			
White blood cell count decreased			

#### Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	12.5 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 24/09/2002	<b>Stopped :</b>	14/07/2004

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Heart Rate				145bpm
White blood cells		10/07/2004	3.9	
White blood cells		19/07/2004	3.4	
Neutrophils		16/07/2004	1.8	
Neutrophils		19/07/2004	1.4	

# Public Case Detail

Cases Count: 393

**Case Number : 232724**

**Data Entry Date :** 29/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 28/02/1982

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** Laboratory tests of WBC and NC were within the normal range.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced myocarditis while on Clozaril. WBC and NC were within the normal range.	Ceased Clozaril

## Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	12.5 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 17/07/2007	<b>Stopped :</b>	



# Public Case Detail

Cases Count: 393

**Case Number : 232731**

**Data Entry Date :** 30/08/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 70

**Onset Date :** 15/07/2007

**Age :**

**DOB :** 31/08/1978

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Left ventricular hypertrophy		Mild left ventricular hypertrophy with good left ventricular function on echo 12/07/07. Toxic clozapine level of 100 on 24/07/07, mild increase QTc of 452 and tachycardia.	Clozapine dose reduced from 700mg to 600mg.
Drug level above therapeutic			
Electrocardiogram QT prolonged			
Tachycardia			

**Medicine details :**

<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	700 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Troponin				LD = normal troponin.
Other data				Heart rate = 112.

## Case Number : 232732

**Data Entry Date :** 30/08/2007

**Gender :** M

**Hospitalisation :** Treated in Accident/Emergency Depar

**Weight (kg) :** 74

**Onset Date :** 20/07/2007

**Age :**

**Outcome :** 24/07/2007

**DOB :** 14/10/1977

Recovered

**Causality :** Causality probable

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Suspected clozapine induced myocarditis, retrosternal chest pain, intermittent tachycardia, low grade temperature, mildly increased eosinophils, ESR increased and CRP increased.	Clozapine ceased.
C-reactive protein increased			
Chest pain			
Eosinophil count increased			
Pyrexia			
Red blood cell sedimentation rate increased			
Tachycardia			
Troponin increased			

#### Medicine details :

<b>CLOZAPINE (Suspected)</b>	<b>Reason :</b> Other myocardial insufficiency		
Tablet	425 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 28/06/2007	<b>Stopped :</b> 23/07/2007	

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin				Troponin peaked at 0.09 21/07/07.
Echocardiogram				Echo normal.

# Public Case Detail

Cases Count: 393

**Case Number : 232872**

**Data Entry Date :** 31/08/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 28/07/1963

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Vomiting		Patient was on Clozaril since 9 Oct 2006. On 14 Aug 2007 the dosage was increased to 550 mg daily which caused the patient to be physically sick (vomiting). Patient ceased taking Clozaril.	Ceased Clozaril
Malaise			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	550 Gram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 09/10/2006	<b>Stopped :</b> 20/08/2007	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
White blood cells				normal
Neutrophils				normal

# Public Case Detail

Cases Count: 393

**Case Number : 232874**

**Data Entry Date :** 31/08/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 28/07/1963

**Outcome :**

**Causality :** Causality probable

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Convulsion		Patient ceased taking Clozaril due to it making her sick. Patient experienced seizures. Patients white blood cell and neutrophils count were within the normal range.	

<b>Medicine details :</b>			
<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b>	
	550 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b> 20/08/2007	0

# Public Case Detail

Cases Count: 393

**Case Number : 232887**

**Data Entry Date :** 03/09/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 08/08/2007

**Age :**

**DOB :** 21/02/1957

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocardial infarction		Myocardial infarction. Patient commenced treatment with Clopine on 25/7/07 for the treatment of schizophrenia. On 8/8/07 patient experienced fever and elevated troponin level which were reported to be mild in intensity. Patient had a myocardial infarction at an unknown date in August 2007 and ceased treatment.	Ceased Clozapine.
Pyrexia			
Troponin increased			

<b>Medicine details :</b>			
<b>CLOZAPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 25/07/2007	<b>Stopped :</b> 09/08/2007	
<b>Aripiprazole (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Troponin				elevated
White blood cells				normal
Troponin		08/08/2007	increased 0.08	

# Public Case Detail

Cases Count: 393

**Case Number : 233069**

**Data Entry Date :** 05/09/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 22/08/2007

**Age :**

**DOB :** 11/05/1983

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Patient commenced treatment with clozapine in April 02 and switched to Clopine in Jan 2007. In August 07 blood tests revealed neutropenia and leucopenia.	Ceased Clopine
Leukopenia			

**Medicine details :**

CLOPINE (Suspected)	Reason :
Tablet	600 Milligram Daily
Batch :	Started : 11/01/2007 Stopped : 22/08/2007

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
White blood cells		26/07/2007	5.70	Dose/mg - 0.0/600.0
White blood cells		22/08/2007	2.70	Dose/mg - 0.0/600.0
Neutrophils		26/07/2007	2.80	Dose/mg - 0.0/600.0
Neutrophils		22/08/2007	0.63	Dose/mg - 0.0/600.0

# Public Case Detail

Cases Count: 393

**Case Number : 233108**

**Data Entry Date :** 06/09/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 04/03/1963

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Breast cancer		Patient developed breast cancer.	Clopine ceased.

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	450 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 19/10/2004	<b>Stopped :</b>	16/07/2007

# Public Case Detail

Cases Count: 393

**Case Number : 233132**

**Data Entry Date :** 06/09/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 30/07/2007

**Age :**

**DOB :** 31/12/1981

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** Patient is hepatitis C positive.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Patient experienced elevated liver functions whilst on Clozaril therapy.	Clozaril ceased.

## Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	575 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 31/05/2007	<b>Stopped :</b>	



# Public Case Detail

Cases Count: 393

**Case Number : 233142**

**Data Entry Date :** 06/09/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**Outcome :** 01/08/2007

**DOB :** 21/01/1950

Recovered

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		Patient experienced agranulocytosis whilst on Clopine and a low neutrophil count after ceasing treatment.	Clopine ceased. Given Stimulating factor and IV meropenem.

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	325 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 13/06/2007	<b>Stopped :</b> 27/07/2007	
<b>ERYTHROMYCIN (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		18/07/2007	6.30	
White blood cells		31/07/2007	4.70	
White blood cells		01/08/2007	9.60	
Neutrophils		18/07/2007	3.50	
Neutrophils		31/07/2007	1.10	
Neutrophils		01/08/2007	4.70	
Other data		18/07/2007	325	Dose(MG)
Other data		31/07/2007	0.0	Dose(MG)
Other data		01/08/2007	0.0	Dose(MG)

# Public Case Detail

Cases Count: 393

**Case Number : 233156**

**Data Entry Date :** 07/09/2007  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 09/08/2007  
**Outcome :** 09/08/2007  
 Death, maybe drug

**Gender :** F  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 25/12/1960  
**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Pneumonia	Death	Patient was admitted to hospital with a pneumonia-related illness and died "a few days" later.	

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	750 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/02/1996	<b>Stopped :</b> 09/08/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 233291**

**Data Entry Date :** 11/09/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 11/09/1976

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Cardiomyopathy		Patient developed low grade cardiomyopathy while on Clozaril.	Clozaril was ceased.

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	12.5 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 01/02/2006	<b>Stopped :</b> 17/08/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 233311**

**Data Entry Date :** 12/09/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 21/08/2007

**Age :**

**DOB :** 23/04/1972

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Intestinal obstruction	Caused or prolonged inpatient hospitalisation	Bowel obstruction. Intestinal obstruction.	

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	12.5 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 20/08/2003	<b>Stopped :</b>	
<b>SODIUM VALPROATE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

**Case Number : 233404**

**Data Entry Date :** 14/09/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 14/11/1961

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:** The patient has a history of stomach ulcer before starting treatment. No concomitant medications.  
The patient has a history of severe reflux and had previous fundoplication >10 years ago. The patient is also Hepatitis C virus (HCV) positive.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Haematemesis	Incapacity/disability	Following Clopine commencement the patient's reflux symptoms increased. He developed haematemesis.	Ceased Clopine treatment.
Condition aggravated	Incapacity/disability		

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	600 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 16/08/2006 <b>Stopped :</b> 01/06/2007
<b>FLUOXETINE HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b> Depression
	20 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>METOCLOPRAMIDE HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b> Nausea and vomiting
	30 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>MULTIVITAMINS (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>THIAMINE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 233411**

**Data Entry Date :** 14/09/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 11/03/1984

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** The patient's white cell and neutrophil counts were generally within the normal ranges, however, occasional high counts had been reported.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion		Patient experienced seizures while on treatment with Clopine.	Clopine was ceased.

## Medicine details :

**CLOPINE (Suspected)**

**Reason :**

Tablet

100 Milligram

Daily

Oral

**Batch :**

**Started :** 16/05/2005

**Stopped :** 17/08/2007

# Public Case Detail

Cases Count: 393

**Case Number : 233425**

**Data Entry Date :** 17/09/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 21/08/2007

**Age :**

**DOB :** 09/02/1930

**Outcome :** 21/08/2007

**Causality :** Causality possible

Death

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction	Death	Patient died of a suspected heart attack.	

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
Tablet	100 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 08/03/2007 <b>Stopped :</b> 21/08/2007

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Neutrophils				Patient's neutrophil counts were within normal ranges for the treatment period, with the exception of a few slightly raised counts.
White blood cells				Patient's white blood cell counts were within normal ranges for the treatment period, with the exception of a few slightly raised counts.

# Public Case Detail

Cases Count: 393

**Case Number : 233546**

**Data Entry Date :** 19/09/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 02/09/1961

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced Myocarditis in August 2007. The patient's white blood cell and neutrophil counts were within normal ranges for the treatment period.	Ceased Clopine.

**Medicine details :**

<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	175 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 08/08/2007	<b>Stopped :</b> 24/08/2007	



# Public Case Detail

Cases Count: 393

**Case Number : 233552**

**Data Entry Date :** 19/09/2007

**Gender :** F

**Hospitalisation :** Required a specialist consultation

**Weight (kg) :** 0

**Onset Date :** 25/07/2007

**Age :**

**DOB :** 05/08/1957

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** Patient's white blood cell counts and neutrophil counts were within normal ranges for the treatment period.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Psoriasis	Caused or prolonged inpatient hospitalisation	Whilst on Clopine and Rulide treatment, patient developed acute psoriasis which was reported to be severe in intensity. Psoriasis gradually developed to a severe rash over trunk, upper and lower limbs and face.	Clopine ceased.

## Medicine details :

<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 20/06/2007	<b>Stopped :</b> 31/08/2007	
<b>RULIDE (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>LITHIUM CARBONATE (Other drug)</b>		<b>Reason :</b> Unspecified psychosis	
Tablet	1 Gram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	L TERM	<b>Stopped :</b>

## Case Number : 233682

Data Entry Date : 21/09/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 06/05/1981

Outcome :

Causality : Causality possible

Unknown

**Information:** Patient was not strict with diabetic diet (ate sweets and chocolates therefore BSL's were fluctuating).

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Type 1 diabetes mellitus	Caused or prolonged inpatient hospitalisation	Insulin Dependent Diabetes, creatine kinase high, morning sedation, ecg abnormal, Tachycardia, White blood cell count increased and neutrophils increased.	Protaphane MC, ceased Clozapine. Switched to aripiprazole and commenced amisulpride and valproate.
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation		
Blood glucose increased	Caused or prolonged inpatient hospitalisation		
Electrocardiogram abnormal	Caused or prolonged inpatient hospitalisation		
Neutrophil count increased	Caused or prolonged inpatient hospitalisation		
Sedation	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

### Medicine details :

<b>CLOZAPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	100 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 05/08/2003 <b>Stopped :</b> Contin

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum glucose				Lab tests conducted throughout the patients treatment showed his blood sugar levels range from 8.7 - 15.9 mmols (ref 4-8)

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography				ECG on 5 May 2006 showed increased sinus rate of approximately 115 bpm. Pulse varied from 87 - 122 bpm.
Creatine phosphokinase				28 Mar 2006, CK ranged from 621 - 728 U/L (ref 0 - 270)
Neutrophils				Neutrophils were $13.00 \times 10^9/L$ (ref 1.8 - 7.5)
Serum drug level				29 Nov 2006 - Clozapine level : 230
White blood cells				WBC ranged from 11.5 - 17.7 (ref 4.0 - 11.0)

# Public Case Detail

Cases Count: 393

**Case Number : 233889**

**Data Entry Date :** 02/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 12/07/1967

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient commenced treatment with Clopine on 16 Aug 2007. During the up-titration the patient developed myocarditis. White blood cell counts and neutrophil counts were within normal ranges for the treatment period.	Clopine ceased.

**Medicine details :**

<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	175 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 16/08/2007	<b>Stopped :</b>	05/09/2007

# Public Case Detail

Cases Count: 393

**Case Number : 233890**

**Data Entry Date :** 02/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**Outcome :**

**DOB :** 10/10/1975

Unknown

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased		Patient developed a CK level of 6008 in Aug/Sep 2007, "since 13 days at 150mg daily" Clozaril.	

**Medicine details :**

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	150 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 13/04/2004	<b>Stopped :</b> 21/02/2007	

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Creatine phosphokinase				Aug 2007 CK: normal. Aug/Sep 2007 CK: 6008.

**Case Number : 233948**

**Data Entry Date :** 02/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 23Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:** The patient underwent pre-clozapine investigations, including an electrocardiogram, echocardiograph, full blood count, hepatic and renal function tests, creatine kinase and troponin I, a CT scan of the brain and electroencephalograph, all of which were normal. Varambally S, Howpage P. Acute myocarditis associated with clozapine. Australian Psychiatry; Aug 2007, 15(4): 343-346.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis, chest pain, heart rate increased, tachycardia, chest discomfort, body temperature increased, troponin increased, blood creatine phosphokinase increased, C-reactive protein increased, dyspnoea, white blood count increased.	All psychiatric medications were ceased. He was placed on low doses of bisoprolol and ramipril by the cardiac team.
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation		
Body temperature increased	Caused or prolonged inpatient hospitalisation		
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Chest discomfort	Caused or prolonged inpatient hospitalisation		
Chest pain	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Heart rate increased	Caused or prolonged inpatient hospitalisation		
Neutrophil count increased	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Troponin I increased	Caused or prolonged inpatient hospitalisation		
Weight increased	Caused or prolonged inpatient hospitalisation		
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

## Medicine details :

### CLOPINE (Suspected)

Reason : Unspecified schizophrenia

12.5 Milligram Daily

Batch :

Started :

Stopped :

0

### FLUOXETINE HYDROCHLORIDE (Suspected)

Reason : Depression

Batch :

Started :

Stopped :

### LITHIUM CARBONATE (Suspected)

Reason : Depression

Batch :

Started :

Stopped :

### OLANZAPINE (Other drug)

Reason :

15 Milligram

Batch :

Started :

Stopped :

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Heart Rate				Heart rate 160/min
Temperature				Body temperature 38.4
Troponin				Troponin I 10.37 (range up to 0.1).
Creatine phosphokinase				Creatine kinase 259 (range up to 171).
C-Reactive Protein				C-Reactive protein 43.2 (range up to 5.0).

# Public Case Detail

Cases Count: 393

**Case Number : 233965**

**Data Entry Date :** 03/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 08/11/1978

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Myocarditis		28 year old male commenced Clopine treatment on approximately 13 Aug 2007 and was taking an unknown dose when he experienced myocarditis.	Clopine treatment was ceased.

**Medicine details :**

<b>CLOZAPINE (Suspected)</b>	<b>Reason :</b>	
Tablet	1 Dose Unspec Daily	Oral
<b>Batch :</b>	<b>Started :</b> 13/08/2007	<b>Stopped :</b> 03/09/2007



# Public Case Detail

Cases Count: 393

**Case Number : 233982**

**Data Entry Date :** 03/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/08/2007

**Age :**

**DOB :** 07/06/1963

**Outcome :** 15/08/2007

**Causality :** Causality possible

Unrelated death

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Death	Death	Patient died while being treated with Clopine therapy.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	500 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/11/2001	<b>Stopped :</b> 15/08/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 233983**

**Data Entry Date :** 03/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 05/09/2007

**Age :**

**DOB :** 15/09/1965

**Outcome :** 05/09/2007

**Causality :** Causality possible

Death

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Death	Death	Patient died due to unexplained reasons whilst being treated with Clopine.	

<b>Medicine details :</b>			
<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	600 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 19/10/2004	<b>Stopped :</b>	05/09/2007

## Case Number : 234130

Data Entry Date : 08/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 26/02/2003

Age :

DOB : 20/07/1948

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Ureteric obstruction		Patient experienced bilateral ureteric criteria, hydronephrosis, blood creatinine increased, blood phosphorus decreased, blood urea increased, blood albumin decreased, creatine phosphokinase increased, blood calcium decreased, colonic faecal loading, abdominal distension, bladder cancer, hepatic function abnormal. unwell, vomiting.	Clozaril ceased.
Abdominal distension			
Bladder cancer			
Blood albumin decreased			
Blood calcium decreased			
Blood creatine phosphokinase increased			
Blood creatinine increased			
Blood phosphorus decreased			
Blood urea increased			
Faecaloma			
Hepatic function abnormal			
Hydronephrosis			
Malaise			
Vomiting			

#### Medicine details :

CLOZARIL (Suspected)

Reason : Unspecified schizophrenia

Tablet

12 Milligram

Daily

Oral

Batch :

Started : 15/08/1994

Stopped : 25/03/2003

# Public Case Detail

Cases Count: 393

**Case Number : 234133**

**Data Entry Date :** 08/10/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 13/01/1976

**Outcome :**

**Causality :** Causality possible

Death

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Death	Patient experienced tachycardia and suspected cardiac re-entry problem.	
Cardiac disorder	Death		

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>	
Tablet	425 Milligram	Daily
		Oral
<b>Batch :</b>	<b>Started :</b> 02/05/2007	<b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 234231**

**Data Entry Date :** 11/10/2007

**Gender :** M

**Hospitalisation :** Treated in Accident/Emergency Depar

**Weight (kg) :** 0

**Onset Date :** 17/09/2007

**Age :**

**DOB :** 05/11/1976

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Tachycardia		Whilst on Clozaril, the patient experienced tachycardia, increased temperature of (38.9c) and hypertension.	
Hypertension			
Pyrexia			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 17/11/2005	<b>Stopped :</b>	Ongoing.
<b>DIAZEPAM (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>ENDEP (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>EPILIM (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>RISPERDAL (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 234232**

**Data Entry Date :** 11/10/2007  
**Hospitalisation :** Admitted to hospital  
**Onset Date :**  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 11/02/1964  
**Causality :** Causality possible

**Information:** Patient's white blood cell and neutrophil counts were within normal limits for the treatment period with exception of a few mildly raised results.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Pneumonia	Caused or prolonged inpatient hospitalisation	Patient developed pneumonia whilst on Clopine therapy.	Treated in intensive care unit.

## Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	800 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 19/01/2004	L TERM	<b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 234243**

**Data Entry Date :** 11/10/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 16/09/2007

**Age :**

**DOB :** 08/02/1968

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
White blood cell count decreased	Caused or prolonged inpatient hospitalisation	Patient commenced Clozaril treatment in Sept 07 for schizophrenia. The patient's dose was currently being titrated. On 16 Sept 07 the patient experienced decreased white blood cell count.	Ceased Clozaril
Neutropenia	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	1 Dose Unspec	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 13/09/2007	<b>Stopped :</b> 16/09/2007	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11)	18/09/2007	2.90	
White blood cells	(4.5-11)	25/09/2007	4.70	
Neutrophils	(1.8-7)	16/09/2007	1.30	
Neutrophils	(1.8-7)	25/09/2007	2.60	

## Case Number : 234246

Data Entry Date : 11/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 18/09/2007

Age :

DOB : 20/06/1958

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Viral infection	Caused or prolonged inpatient hospitalisation	Patient was taking Clozaril for the treatment of Schizophrenia. On 18 Sep 07 the patient experienced fever, viral symptoms, and a decreased white blood cell count.	Clozaril was ceased.
Neutropenia	Caused or prolonged inpatient hospitalisation		
White blood cell count decreased	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	12 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 20/01/1999	<b>Stopped :</b>	18/09/2007

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11)	15/09/2007	2.95	
Neutrophils		18/09/2007	0.84	



## Case Number : 234260

Data Entry Date : 11/10/2007

Hospitalisation :

Onset Date : 13/09/2007

Outcome :  
Recovered

Gender : M

Weight (kg) : 0

Age :

DOB : 27/09/1951

Causality : Causality possible

### Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient experienced flu like symptoms and vomiting. The patient was detected to have blood creatine phosphokinase increased, troponin T increased, C-reactive protein increased and myocarditis.	Treatment ceased 17/09/07.
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation		
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Influenza like illness	Caused or prolonged inpatient hospitalisation		
Troponin T increased	Caused or prolonged inpatient hospitalisation		
Vomiting	Caused or prolonged inpatient hospitalisation		

Medicine details :			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 30/08/2007	<b>Stopped :</b> 17/09/2007	
<b>Abilify (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Creatine phosphokinase		17/09/2007	1156	
Troponin		17/09/2007	0.201	
C-Reactive Protein		17/09/2007	336	

## Case Number : 234262

Data Entry Date : 11/10/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 09/09/2007

Age :

DOB : 14/10/1975

Outcome : 19/09/2007

Causality : Causality probable

Recovered

**Information:** The reporter indicated that all pre-clozapine tests (including WCC and neutrophil count) were normal

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia	Caused or prolonged inpatient hospitalisation	Patient commenced Clopine treatment on 6 Sept 07. On 9 Sept 07 she presented to the ED with flu like symptoms and a high fever. She was assessed and found to have a 'spot on her lungs' and diagnosed with pneumonia. She was discharged home with a course of antibiotics. Her symptoms deteriorated further. She had a persistent wet cough, productive of green sputum and feeling very lethargic and feverish. The patient returned to the Clinic for her day 7 Clopine review. On examination, she was very tired, irritable and pale. There was a postural drop in her BP and she had tachycardia.	Ceased Clopine. Amoxicillin. IV antibiotics.
Lethargy	Caused or prolonged inpatient hospitalisation		
Leukopenia	Caused or prolonged inpatient hospitalisation		
Pallor	Caused or prolonged inpatient hospitalisation		
Pneumonia	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

## Medicine details :

### CLOPINE (Suspected)

Reason : Unspecified schizophrenia

Tablet 150 Milligram Daily Oral

Batch : Started : 06/09/2007 Stopped : 13/09/2007

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### Risperdal Consta (Other drug)

Reason : Unspecified schizophrenia

Injection 62.5 Milligram Fortnightly Intramuscular

Batch : Started : Stopped : Contin

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### SODIUM VALPROATE (Other drug)

Reason :

1.5 Gram Oral

Batch : Started : Stopped :

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## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		13/09/2007	3.70	
White blood cells		19/09/2007	6.70	
Neutrophils		13/09/2007	1.87	
Neutrophils		19/09/2007	3.40	

# Public Case Detail

Cases Count: 393

**Case Number : 234263**

**Data Entry Date :** 11/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 20/01/1979

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** The patient's white blood cell (WBC) and neutrophil counts (NC) were slightly elevated around the time of the event.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		The patient commenced Clozapine treatment on 3 July 2001 and switched to Clopine on 30 Nov 2006. The patient's white blood cell and neutrophil counts were slightly elevated around the time of the event.	Ceased Clopine

## Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	275 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 30/11/2006	<b>Stopped :</b>	12/09/2007

# Public Case Detail

Cases Count: 393

## Case Number : 234264

Data Entry Date : 11/10/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 10/09/2007

Age :

DOB : 03/09/1971

Outcome :

Causality : Causality possible

Not yet recovered

**Information:** The patient's white blood cell and neutrophil counts were elevated on a number of occasions throughout her treatment period.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Pneumonia	Caused or prolonged inpatient hospitalisation	Patient developed pneumonia whilst on Clopine.	Admitted to the intensive care unit, required intubation.

### Medicine details :

<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 04/01/2007	<b>Stopped :</b>	

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		01/02/2007	22.9	
White blood cells		15/08/2007	13.5	
Neutrophils		01/02/2007	19.0	
Neutrophils		15/08/2007	9.2	

# Public Case Detail

Cases Count: 393

**Case Number : 234265**

**Data Entry Date :** 11/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 05/09/2007

**Age :**

**DOB :** 12/01/1978

**Outcome :** 05/09/2007

**Causality :** Causality possible

Death

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Death	Death	Patient commenced Clozapine on 21 Sept 2005 and switched to Clopine on 26 Sept 2006. He titrated up to a dose of 300mg daily and continued treatment until his death on 5 Sept 2007.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 26/09/2006	<b>Stopped :</b>	05/09/2007

**Case Number : 234372**

**Data Entry Date :** 15/10/2007

**Gender :** F

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 25/03/1988

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** History: mental impairment, deterioration of mental state, predominantly hearing voices and velo-cardio-facial syndrome.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Dilatation ventricular	Caused or prolonged inpatient hospitalisation	Patient experienced a mildly dilated left ventricle, irregular heart rate, blood pressure fluctuation, anaemia, infection, C-reactive protein increased, red blood cell sedimentation rate increased, pyrexia, blood creatine phosphokinase increased, hypoparathyroidism, hypocalcaemia, metal impairment, lower respiratory tract infection, white blood cell count decreased, neutropenia and lymphocyte count decreased.	
Anaemia	Caused or prolonged inpatient hospitalisation		
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation		
Blood pressure fluctuation	Caused or prolonged inpatient hospitalisation		
C-reactive protein increased	Caused or prolonged inpatient hospitalisation		
Heart rate irregular	Caused or prolonged inpatient hospitalisation		
Hypocalcaemia	Caused or prolonged inpatient hospitalisation		
Hypoparathyroidism	Caused or prolonged inpatient hospitalisation		
Infection	Caused or prolonged inpatient hospitalisation		

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Lower respiratory tract infection	Caused or prolonged inpatient hospitalisation		
Lymphocyte count decreased	Caused or prolonged inpatient hospitalisation		
Mental impairment	Caused or prolonged inpatient hospitalisation		
Neutropenia	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Red blood cell sedimentation rate increased	Caused or prolonged inpatient hospitalisation		
White blood cell count decreased	Caused or prolonged inpatient hospitalisation		

## Medicine details :

**CLOZARIL (Suspected)**

**Reason :** Unspecified schizophrenia

Tablet

75 Milligram

Daily

Oral

**Batch :**

**Started :** 20/03/2006

**Stopped :** 25/05/2006

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Magnetic Resonance Imaging				Magnetic resonance imaging (MRI) changes suggesting white matter lesions.



## Case Number : 234386

Data Entry Date : 15/10/2007

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 12/04/2007

Age :

DOB : 08/04/1954

Outcome :

Causality : Causality possible

Unknown

**Information:** History: smoker, obesity, diabetes mellitus and hypercholesterolaemia.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Iron deficiency anaemia	Caused or prolonged inpatient hospitalisation	Patient developed anaemia, mean cell haemoglobin decreased, heamoglobin decreased, haematocrit decreased, red blood cell count decreased, mean cell volume decreased, mental disorder, echocardiogram abnormal, troponin 1 increased, hypoxia, fatigue, respiratory tract infection, pyrexia, blood sodium increased, blood chloride decreased, blood potassium decreased, anion gap increased, blood urea increased, blood magnesium decreased and lymphocyte count decreased.	Clozaril ceased. Treated with IV ceftriaxone, azithromycin, augmentin DF and doxycycline.
Anion gap increased	Caused or prolonged inpatient hospitalisation		
Blood chloride decreased	Caused or prolonged inpatient hospitalisation		
Blood magnesium decreased	Caused or prolonged inpatient hospitalisation		
Blood potassium decreased	Caused or prolonged inpatient hospitalisation		
Blood sodium increased	Caused or prolonged inpatient hospitalisation		
Blood urea increased	Caused or prolonged inpatient hospitalisation		
Echocardiogram abnormal	Caused or prolonged inpatient hospitalisation		
Fatigue	Caused or prolonged inpatient hospitalisation		

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Haematocrit decreased	Caused or prolonged inpatient hospitalisation		
Haemoglobin decreased	Caused or prolonged inpatient hospitalisation		
Hypoxia	Caused or prolonged inpatient hospitalisation		
Lymphocyte count decreased	Caused or prolonged inpatient hospitalisation		
Mean cell haemoglobin decreased	Caused or prolonged inpatient hospitalisation		
Mean cell volume decreased	Caused or prolonged inpatient hospitalisation		
Mental disorder	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Red blood cell count decreased	Caused or prolonged inpatient hospitalisation		
Respiratory tract infection	Caused or prolonged inpatient hospitalisation		
Troponin I increased	Caused or prolonged inpatient hospitalisation		

## Medicine details :

### CLOZARIL (Suspected)

Reason : Unspecified schizophrenia

Tablet 12.5 Milligram Daily Oral  
Batch : Started : 29/04/2002 Stopped : 16/08/2007

### ASPIRIN (Other drug)

Reason :

Batch : Started : Stopped : Oral

### COLOXYL WITH SENNA (Other drug)

Reason :

Tablet Batch : Started : Stopped : Oral

### FRUSEMIDE (Other drug)

Reason :

Batch : Started : Stopped :

### GLICLAZIDE (Other drug)

Reason :

Tablet Batch : Started : Stopped : Oral

### GLYCERYL TRINITRATE (Other drug)

Reason :

Batch : Started : Stopped :

## Medicine details :

METFORMIN HYDROCHLORIDE (Other drug)

Reason :

Tablet

Oral

Batch :

Started :

Stopped : 16/08/2007

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram		16/07/2004	Mild calcified aortic stenosis.	Echocardiogram: Left anterior descending artery has minor irregularity. The right coronary artery has some mild plaque proximally with a further proximal to mild vessel eccentric 60% stenosis. Calcified aortic valve with restricted movement. Aortic valve gradient of 52 at pullback.
Echocardiogram		18/08/2005	Moderate aortic stenosis.	Echocardiogram: Left anterior descending artery has minor irregularity. The right coronary artery has some mild plaque proximally with a further proximal to mild vessel eccentric 60% stenosis. Calcified aortic valve with restricted movement. Aortic valve gradient of 52 at pullback.
Echocardiogram		05/01/2006	Borderline to severe aortic stenosis.	Echocardiogram: Left anterior descending artery has minor irregularity. The right coronary artery has some mild plaque proximally with a further proximal to mild vessel eccentric 60% stenosis. Calcified aortic valve with restricted movement. Aortic valve gradient of 52 at pullback.
Echocardiogram		12/04/2007	Mild left atrial enlargement severe aortic stenosis.	Echocardiogram: Left anterior descending artery has minor irregularity. The right coronary artery has some mild plaque proximally with a further proximal to mild vessel eccentric 60% stenosis. Calcified aortic valve with restricted movement. Aortic valve gradient of 52 at pullback.
Sodium	(135-145)	17/08/2007	146 mmol/L	
Sodium	(135-145)	18/08/2007	150 mmol/L	
Potassium	(3.5-5.0)	17/08/2007	3.2 mmol/L	
Troponin	(<0.040)	16/08/2007	0.839 ug/L	Troponin 1
Troponin	(<0.040)	16/08/2007	0.873 ug/L	Troponin 1
Troponin	(<0.040)	17/08/2007	0.778 ug/L	Troponin 1

# Public Case Detail

Cases Count: 393

**Case Number : 234431**

**Data Entry Date :** 16/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 23/08/2007

**Age :**

**DOB :** 31/07/1986

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** Current condition substance abuse alcohol and drugs.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Hepatic enzyme increased		Patient experienced elevated liver enzymes.	Clozaril dose was decreased.

## Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 19/07/2007	<b>Stopped :</b>	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
AST = SGOT	(5-40)	24/08/2007	90	
ALT = SGPT	(5-40)	24/08/2007	204	
GGT = SGGT = GGTP	(1-65)	24/08/2007	99	

# Public Case Detail

Cases Count: 393

**Case Number : 234547**

**Data Entry Date :** 18/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 12/06/2007

**Age :**

**DOB :** 22/05/1981

**Outcome :**

**Causality :** Causality probable

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Eosinophilia		Patient experienced eosinophilia.	Clozaril was ceased.

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	12.5 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 23/05/2007	<b>Stopped :</b> 02/07/2007	
<b>SODIUM VALPROATE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b> 01/06/2007	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Eosinophils		03/04/2007	0.6	
Eosinophils		18/06/2007	1.5	
Eosinophils		29/06/2007	8.2	

# Public Case Detail

Cases Count: 393

**Case Number : 234552**

**Data Entry Date :** 18/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 31/08/2007

**Age :**

**DOB :** 21/02/1945

**Outcome :** 31/08/2007

**Causality :** Causality possible

Death, maybe drug

**Information:** Severe parkinson's disease (end stage) with severe physical disability requiring nursing home care since 2005. He had deafness and a long history of schizophrenia.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident	Death	Patient experienced a cerebrovascular accident.	

## Medicine details :

<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 06/04/2006	<b>Stopped :</b> 31/08/2007	
<b>DIAZEPAM (Suspected)</b>		<b>Reason :</b>	
Tablet	4 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 234561**

**Data Entry Date :** 18/10/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/09/2007

**Age :**

**DOB :** 25/10/1971

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** White blood cell counts (WCC) and neutrophil counts (NC) were within normal ranges for the treatment period.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient was taking Clopine 50mg daily at time of Myocarditis.	Ceased treatment with Clopine

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	50 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 11/09/2007	<b>Stopped :</b> 26/09/2007	

## Case Number : 234562

**Data Entry Date :** 18/10/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 54.5

**Onset Date :** 14/09/2007

**Age :**

**DOB :** 29/06/1942

**Outcome :** 17/09/2007

**Causality :** Causality probable

Unrelated death

**Information:** Her white blood cell (WBC) and neutrophil counts (NC) were within normal ranges for the treatment period.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient had previous low grade fever while treated with Clopine. Patient was on dose of 150mg when she experienced echocardiogram which showed mild increase in septal thickness.	Discontinued Clopine
Echocardiogram abnormal			
Pyrexia			

### Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	150 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 30/08/2007	<b>Stopped :</b> 17/09/2007	



## Case Number : 234563

Data Entry Date : 18/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 26/09/2007

Age :

DOB : 23/09/1976

Outcome :

Causality : Causality possible

Not yet recovered

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Patient commenced treatment with Clozapine and switched to Clopine on 10 Nov 2006. He was taking 900mg daily at the time of Neutropenia, leucopenia.	Ceased Clopine
Neutropenia			

#### Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	900 Milligram Daily
Batch :	Started : 10/11/2006
	Stopped : 26/09/2007

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		21/09/2007	3.50	
White blood cells		26/09/2007	2.40	
White blood cells		27/09/2007	2.40	
White blood cells		30/09/2007	2.50	
Neutrophils		21/07/2007	1.52	
Neutrophils		26/09/2007	1.52	
Neutrophils		27/09/2007	0.60	
Neutrophils		30/09/2007	0.66	

# Public Case Detail

Cases Count: 393

**Case Number : 234564**

**Data Entry Date :** 18/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 22/09/2007

**Age :**

**DOB :** 21/07/1964

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** The patient's white blood cell and neutrophil count were within normal ranges for the treatment period.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Confusional state	Caused or prolonged inpatient hospitalisation	Patient experienced confusion and delirium while on Clopine therapy. On admission to hospital patient had a fever and was also found to be tachycardic and hypotensive. Myocarditis was suspected.	IV ceftriaxone. Augmentin.
Delirium	Caused or prolonged inpatient hospitalisation		
Hypotension	Caused or prolonged inpatient hospitalisation		
Myocarditis	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 24/04/2007	<b>Stopped :</b>	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography				There were no changes in the electrocardiogram (ECG).

# Public Case Detail

Cases Count: 393

**Case Number : 234631**

**Data Entry Date :** 22/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 05/09/1989

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Pericarditis		Patient experienced pericarditis, tachycardia, increased CK, eosinophilia, weight gain and hypersalivation.	Clozaril discontinued.
Blood creatine phosphokinase increased			
Eosinophilia			
Salivary hypersecretion			
Tachycardia			
Weight increased			

**Medicine details :**

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	250 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 17/09/2007	<b>Stopped :</b>	03/10/2007

# Public Case Detail

Cases Count: 393

**Case Number : 234634**

**Data Entry Date :** 22/10/2007

**Gender :** M

**Hospitalisation :** Required a visit to the doctor

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 23/01/1981

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Cardiomyopathy		Routine check up including chest X-ray showed cardiomyopathy. Patient had no symptoms. ECG - sinus tachycardia. Clozapine induced Myocarditis.	
Electrocardiogram abnormal			
Myocarditis			
Sinus tachycardia			

<b>Medicine details :</b>			
<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>DIABEX (Other drug)</b>		<b>Reason :</b> Diabetes mellitus	
Tablet	1 Gram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Creatine phosphokinase				Normal
Troponin				Normal
Chest X-ray				Showed cardiomyopathy.

# Public Case Detail

Cases Count: 393

**Case Number : 234641**

**Data Entry Date :** 22/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 04/10/2007

**Age :**

**DOB :** 12/04/1978

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** White blood cell counts (WCC) and neutrophil counts (NC) were within normal ranges for the treatment period.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient commenced Clopine on 15 August 2007 and ceased treatment due to myocarditis.	Ceased treatment

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	275 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/08/2007	<b>Stopped :</b> 04/10/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 234642**

**Data Entry Date :** 22/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 04/01/1967

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** White blood cells (WCC) and neutrophil counts (NC) were within normal ranges for the treatment period.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	The patient commenced treatment with Clozapine on 29 Oct 2002 and switched to Clopine on 24 Feb 2004. He was taking a dose of 800mg daily and ceased treatment on 3 October due to cardiomyopathy.	Ceased treatment. Treated in ICU.

## Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	800 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 29/10/2002	<b>Stopped :</b>	03/10/2007

**Case Number : 234648**

**Data Entry Date :** 22/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/09/2007

**Age :**

**DOB :** 14/08/1962

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** Other drug taken: Acetylsalicylate Calcium. History of diabetes, hyperlipidaemia and mild left ventricular hypertrophy. Patient's white blood cell and neutrophil counts have been within limits for the treatment period with the exception of a few mildly raised results. Patient has been on clozapine for 14 years and the reporter noted that patient is of high coronary risk. He also has diabetes and hyperlipidaemia. Patient has had no previous cardiac problems with normal left ventricular function on previous echocardiograms (Echo) in 2005 and 2006. Echo in 2005 suggested mild left ventricular hypertrophy.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Pericarditis		Patient experienced an enlarged heart whilst on Clopine treatment, mild cardiac enlargement and left pleural effusion, anaemia, rouleaux, left ventricular hypertrophy, neutrophil toxic granulation and abnormal ecg.	Clopine ceased.
Anaemia			
Cardiomegaly			
Electrocardiogram abnormal			
Left ventricular hypertrophy			
Myocarditis			
Neutrophil toxic granulation present			
Pleural effusion			
Rouleaux formation			

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	300 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 27/04/1993 L TERM <b>Stopped :</b> 02/10/2007 0
<b>ATORVASTATIN (Other drug)</b>	<b>Reason :</b>
Tablet	Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>Glucovance 500/2.5 (Other drug)</b>	<b>Reason :</b>
Tablet	Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

<b>Medicine details :</b>		
ROSIGLITAZONE (Other drug)	Reason :	
Tablet	Oral	
Batch :	Started :	Stopped :

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Other data				(CXR) was completed (15/09/07) suggesting mild cardiac enlargement and left pleural effusion. (CXR) 10 days later (25/09/07) showed 'massively enlarged' heart including left atrium and both ventricles, but no pleural effusion.
White blood cells		01/10/2007	12.3 x 10 <sup>9</sup> /L	
Neutrophils		01/10/2007	8.9 x 10 <sup>9</sup> /L	
Haemoglobin		01/10/2007	11.7	Hb



## Case Number : 234689

Data Entry Date : 23/10/2007

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 15/08/2007

Age :

DOB : 06/07/1952

Outcome :

Causality : Causality possible

Recovered

**Information:** Past history of heavy alcohol use, sensitivity to penicillin (facial swelling). Known history of non compliance with medication.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	Patient experienced cardiac complications, was diagnosed with cardiomyopathy, hypokinesia left atrial enlargement, and progressive left ventricular failure.	Clozaril discontinued. Treated with Carvedilol 3.125mg/twice daily.
Ejection fraction decreased	Caused or prolonged inpatient hospitalisation		
Left atrial dilatation	Caused or prolonged inpatient hospitalisation		
Left ventricular failure	Caused or prolonged inpatient hospitalisation		

### Medicine details :

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	150 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 28/04/2007 <b>Stopped :</b> 15/08/2007
<b>OLANZAPINE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase	(0-240)	16/08/2007	51	Pretreatment CK = 44. Global systolic function of 50%. On the 16/08/07 the patient's creatine Kinase (CK) was measured within reference range.

## Case Number : 234723

Data Entry Date : 23/10/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 30/04/1962

Outcome :

Causality : Causality possible

Unknown

**Information:** These symptoms are in contrast to the normal echocardiogram one month ago.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient presented tachycardic, clammy and sweating. We was febrile, lethargic, unwell and had decreased intake. The doctor diagnosed the patient with having suspected myocarditis.	
Blood creatine phosphokinase increased			
Lethargy			
Pyrexia			
Tachycardia			

### Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecifid affective psychosis		
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 19/09/2007	<b>Stopped :</b>	
<b>CARBAMAZEPINE (Other drug)</b>	<b>Reason :</b> Unspecifid affective psychosis		
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Blood pressure				148 bpm.
Troponin				0.38
Creatine phosphokinase				CK 170
White blood cells				White blood cell and neutrophil counts were normal throughout the treatment period.

# Public Case Detail

Cases Count: 393

**Case Number : 234736**

**Data Entry Date :** 23/10/2007

**Gender :** M

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Onset Date :** 09/10/2007

**Age :**

**DOB :** 07/04/1948

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Pneumonia aspiration	Caused or prolonged inpatient hospitalisation	Patient was hospitalised for a bowel obstruction and pneumonia and suffered from constipation.	Clozaril temporarily ceased for more than 4 days.
Constipation	Caused or prolonged inpatient hospitalisation		
Lymphocyte count decreased	Caused or prolonged inpatient hospitalisation		
Neutrophil count decreased	Caused or prolonged inpatient hospitalisation		
Red cell distribution width increased	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	700 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 23/12/1999	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Lymphocytes	(1.2 - 4.0 x 10 <sup>9</sup> /L)	09/10/2007	04x10 <sup>9</sup> /L	

# Public Case Detail

Cases Count: 393

**Case Number : 234773**

**Data Entry Date :** 25/10/2007

**Gender :** M

**Hospitalisation :** Treated in Accident/Emergency Depar

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 28/03/1977

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** History of raised white cell counts whilst being treated with Clopine.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Intestinal perforation	Caused or prolonged inpatient hospitalisation	Patient experienced acute abdominal pain and was taken to emergency department. The patient was found to have faecal impaction and upon further investigation, a bowel perforation.	Admitted to Intensive Care Unit..
Faecaloma	Caused or prolonged inpatient hospitalisation		

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
Tablet	425 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 26/07/2007 <b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 234789**

**Data Entry Date :** 25/10/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 11/02/1970

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** The patient's white blood cell and neutrophil counts were above the normal ranges throughout treatment, though baseline levels were also elevated.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient commenced Clopine treatment and developed myocarditis.	Clopine ceased.

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 25/09/2007	<b>Stopped :</b>	11/10/2007

## Case Number : 234938

Data Entry Date : 01/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 05/09/2007

Age :

DOB : 09/02/1957

Outcome :

Causality : Causality possible

Unknown

### Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Life threatening	Patient commenced Clopine treatment on 20 Aug 2007. On 5 Sept 2007 the patient was found to have a high grade fever and mild pedal oedema. Patient was tachycardic and his troponin T, creatine kinase and c-reactive protein were all elevated. Patient was therefore clinically diagnosed to have acute cardiac failure, however the reporting medical practioner considered the underlying cause to be myocarditis. Patient also had low haemoglobin. Red cells showed increased rouleaux. Also marked eosinophilia.	Frusemide, perindopril, carvedilol and cessation of Clopine.
Blood creatine phosphokinase increased	Life threatening		
Cardiac failure	Life threatening		
Eosinophilia	Life threatening		
Haemoglobin decreased	Life threatening		
Oedema peripheral	Life threatening		
Pyrexia	Life threatening		
Rouleaux formation	Life threatening		
Tachycardia	Life threatening		
Troponin T increased	Life threatening		

### Medicine details :

<b>CLOPINE (Suspected)</b>		<b>Reason : Unspecified schizophrenia</b>	
Tablet	275 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started : 21/08/2007</b>	<b>Stopped : 07/09/2007</b>	

## Medicine details :

RISPERIDONE (Other drug)

Reason :

Injection

Batch :

Started : 01/03/2007

Stopped :

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Ejection fraction		05/09/2007	31%	

## Case Number : 234959

Data Entry Date : 01/11/2007

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 08/10/2007

Age :

DOB : 27/05/1936

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased		Patient had a chest infection. White blood cell count decreased while being treated with Clozaril.	Antibiotics
Lower respiratory tract infection			
Neutrophil count decreased			

#### Medicine details :

CLOZAPINE (Suspected)	Reason :
Tablet	300 Milligram Daily Oral
Batch :	Started : 21/06/2006 Stopped : 08/10/2007

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		10/10/2007	2.40 (reference 4.5-11 x 10 <sup>9</sup> /L)	
White blood cells		09/10/2007	2.80	
White blood cells		08/10/2007	3.00	
Neutrophils		08/10/2007	0.70 (reference 1.8-7.7x10 <sup>9</sup> /L)	
Neutrophils		08/10/2007	1.70	
Neutrophils		08/10/2007	1.90	



# Public Case Detail

Cases Count: 393

**Case Number : 234993**

**Data Entry Date :** 02/11/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 13/04/1963

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Pericardial effusion	Caused or prolonged inpatient hospitalisation	Patient was hospitalised for "gastro" and had developed eosinophilla. The patient also had "a tiny myocardial effusion". It was also noted that the patient had "myoclonic jerks - facial". These symptoms had coincided with the addition of ciprofloxacin for the gastro.	
Myoclonus	Caused or prolonged inpatient hospitalisation		

**Medicine details :**

<b>CIPROFLOXACIN (Suspected)</b>		<b>Reason :</b>	
		1 Dose Unspec Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	50 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started : 27/07/2007</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 235006**

**Data Entry Date :** 02/11/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 19/10/2007

**Age :**

**DOB :** 15/06/1970

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Influenza like illness		Patient complaining of aching pains, documented postural hypotension since Clozapine initiation, tachycardia, development of flu-like symptoms.	Clozapine ceased. Metoprolol started. Pt referred to ED for cardiology.
Orthostatic hypotension			
Tachycardia			

**Medicine details :**

<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia		
Tablet	300 Milligram	Daily	Oral	
<b>Batch :</b>	<b>Started :</b> 11/10/2007	<b>Stopped :</b> 23/10/2007	0	
<b>RISPERIDONE (Other drug)</b>		<b>Reason :</b> Unspecified schizophrenia		
Tablet	37.5 Milligram	Daily	Oral	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>		

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Troponin		23/10/2007	0.25	
Troponin		24/10/2007	0.24	
Troponin		25/10/2007	0.16	

# Public Case Detail

Cases Count: 393

**Case Number : 235016**

**Data Entry Date :** 05/11/2007

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Gender :** M

**Weight (kg) :** 0

**Age :** 99U

**DOB :**

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Orthostatic hypotension		Patient developed Addison's disease and orthostatic hypotension whilst being treated with Clopine.	
Addison's disease			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	650 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Blood pressure				low

# Public Case Detail

Cases Count: 393

**Case Number : 235034**

**Data Entry Date :** 05/11/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 11/11/1984

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased		Patient was taking Clozaril since 8 October 2003. The reporter stated that the patient had missed nine days of treatment. The physician conducted routine blood tests and this indicated that the patient's CK levels had risen sharply.	

**Medicine details :**

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	500 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 08/10/2003	<b>Stopped :</b>	

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		15/08/2007	305	(Date not provided, recen test) CK:1341.
White blood cells				White blood cells count were all within normal range.
Neutrophils				Neutrophil count levels were all within normal range.
Troponin				Troponin levels were all within normal range.

# Public Case Detail

Cases Count: 393

**Case Number : 235035**

**Data Entry Date :** 05/11/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 16/10/2007

**Age :**

**DOB :** 26/01/1954

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Lower respiratory tract infection		Patient experienced chest infection and right pleural effusion whilst on Clozaril. The patient's blood tests showed elevated White Blood Cell counts and elevated Neutrophil counts.	
Neutrophil count increased			
Pleural effusion			
White blood cell count increased			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 22/07/1994	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
White blood cells		16/10/2007	38.90	
Neutrophils		16/10/2007	34.80	

## Case Number : 235064

Data Entry Date : 07/11/2007

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 16/10/2007

Age :

DOB : 28/03/1977

Outcome :

Causality : Causality possible

Not yet recovered

Information: Has a temporary colostomy bag.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Constipation	Life threatening	Sudden onset of testicular and abdominal pain which escalated rapidly, with findings of a rigid abdomen. He required surgery - found to be severely constipated with a rupture of the colon and faeces within abdominal cavity.	Surgery.
Large intestine perforation	Life threatening		
Peritonitis	Life threatening		

### Medicine details :

<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	425 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 27/07/2007	<b>Stopped :</b> 16/10/2007	0
<b>HALOPERIDOL (Other drug)</b>		<b>Reason :</b> Unspecified schizophrenia	
	20 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b> 18/04/2007	<b>Stopped :</b>	0
<b>LITHIUM CARBONATE (Other drug)</b>		<b>Reason :</b> Unspecified schizophrenia	
	750 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	L TERM	<b>Stopped :</b> 0

# Public Case Detail

Cases Count: 393

**Case Number : 235143**

**Data Entry Date :** 09/11/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 11/04/1971

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Cerebrovascular accident		Patient commenced Clozapine on 23 Nov 2006 and switched to Clopine on 12 July 07. Patient experienced a stroke.	Ceased Clopine.

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 12/07/2007	<b>Stopped :</b> 06/10/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 235264**

**Data Entry Date :** 14/11/2007

**Gender :** M

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Onset Date :** 24/10/2007

**Age :**

**DOB :** 09/08/1951

**Outcome :**

**Causality :** Causality probable

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Syncope	Caused or prolonged inpatient hospitalisation	Patient experienced a collapse, seizure and increased blood clozapine levels whilst on Clopine treatment.	Clopine dose reduced to 300mg.
Convulsion	Caused or prolonged inpatient hospitalisation		
Drug level above therapeutic	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	600 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 18/07/2000	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Serum drug level				A Clozapine blood level was found to be 1365 ug/L and norclozapine 676 ug/L. This was described as 'toxic' by the reporter.



# Public Case Detail

Cases Count: 393

**Case Number : 235414**

**Data Entry Date :** 19/11/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 26/10/2007

**Age :**

**DOB :** 14/01/1961

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** Patient later died from the cardiac event which was not related to Clozaril but was due to an abscess on the heart.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Pericardial effusion		Patient experienced cardiac complications - pericardial effusion.	Clozaril ceased.

## Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	800 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 10/06/1993	<b>Stopped :</b> 26/10/2007	0

# Public Case Detail

Cases Count: 393

**Case Number : 235432**

**Data Entry Date :** 20/11/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/10/2007

**Age :**

**DOB :** 15/06/1970

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Left ventricular hypertrophy		Cardiac complications, including left ventricular hypertrophy (shown on echo) and myocarditis.	Ceased therapy.
Echocardiogram abnormal			
Myocarditis			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 11/10/2007	<b>Stopped :</b> 24/10/2007	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Echocardiogram				Echo: Left ventricular hypertrophy, myocarditis.

## Case Number : 235460

**Data Entry Date :** 20/11/2007  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 08/03/2007  
**Outcome :** 19/03/2007  
 Recovered

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 07/11/1940  
**Causality :** Causality possible

### Information:

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Asthenia	Life threatening		
Malaise	Life threatening		
Pneumonia mycoplasmal			doxycycline
Pyrexia	Life threatening		
Tachycardia	Life threatening		

### Medicine details :

<b>CLOZAPINE (Suspected)</b>	<b>Reason :</b>
Tablet	200 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 20/02/2007 <b>Stopped :</b> 08/03/2007
<b>EPILIM (Other drug)</b>	<b>Reason :</b>
	500 Milligram
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>OMEPRAZOLE (Other drug)</b>	<b>Reason :</b>
	20 Milligram
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>PARACETAMOL (Other drug)</b>	<b>Reason :</b>
	1 Gram
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				CRP = 174 WCC = 10 ESR high Pathology positive for mycoplasma pneumonia and commenced on doxycycline for 2 weeks 100mg bd
Electrocardiography				TTE showed normal LC size with low normal systolic function

# Public Case Detail

Cases Count: 393

**Case Number : 235473**

**Data Entry Date :** 21/11/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 20/08/2007

**Age :**

**DOB :** 13/05/1976

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** The patient was previously treated with Clopine and ceased treatment due to cardiomyopathy. The patient's white blood cell and neutrophil counts were within acceptable limits for the treatment period.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced myocarditis and cardiac chest pain.	Ceased clozapine.
Chest pain			

## Medicine details :

**CLOPINE (Suspected)**

**Reason :**

Tablet

37.5 Milligram

Daily

Oral

**Batch :**

**Started :** 20/08/2007

**Stopped :** 24/08/2007

0

**Case Number : 235498****Data Entry Date :** 21/11/2007**Gender :** M**Hospitalisation :****Weight (kg) :** 0**Onset Date :** 10/10/2007**Age :****DOB :** 30/07/1977**Outcome :****Causality :** Causality certain

Not yet recovered

**Information:** Suspected drug is cert/rechallenge. Patient's white cell and neutrophil counts were within the normal ranges throughout treatment. Full blood count, electrolytes, urea and creatinine, liver functions tests, troponin I, urine culture, blood culture and chest x-ray were all normal.

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Patient experienced mild blurred vision, severe high fever of (>39c), severe tachycardia (>150HR) and postural hypotension (90/60).	
Tachycardia			
Vision blurred			

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	50 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 10/10/2007	<b>Stopped :</b>	Continuing.
<b>RISPERIDONE (Other drug)</b>	<b>Reason :</b> Unspecified psychosis		
	2 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 235499**

**Data Entry Date :** 21/11/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 05/11/2007

**Age :**

**DOB :** 29/06/1967

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Neutropenia		Patient experienced severe neutropenia and moderate leukopenia.	Clopine ceased.
Leukopenia			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 10/08/2007	<b>Stopped :</b> 05/11/2007	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
White blood cells		06/11/2007	2.30	
White blood cells		05/11/2007	2.10	
White blood cells		23/10/2007	4.60	
Neutrophils		06/11/2007	0.85	
Neutrophils		05/11/2007	0.84	
Neutrophils		23/10/2007	2.51	
Other data		06/11/2007	0.0	Dose
Other data		05/11/2007	0.0	Dose
Other data		23/10/2007	400.0	Dose

# Public Case Detail

Cases Count: 393

**Case Number : 235500**

**Data Entry Date :** 21/11/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 29/10/2007

**Age :**

**DOB :** 12/11/1983

**Outcome :** 29/10/2007

**Causality :** Causality possible

Unrelated death

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Death	Death	Death unexplained.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	350 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 03/01/2007	<b>Stopped :</b> 29/10/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 235503**

**Data Entry Date :** 21/11/2007

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 26/10/2007

**Age :**

**DOB :** 02/06/1954

**Outcome :** 26/10/2007

**Causality :** Causality possible

Unrelated death

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Death	Death	Death unexplained.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 06/11/2006	<b>Stopped :</b>	



## Case Number : 235572

Data Entry Date : 23/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 01/11/2007

Age :

DOB : 18/08/1966

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased		Patient experienced a decrease in his white blood cell count.	Clozaril discontinued.
Agranulocytosis			

#### Medicine details :

CLOZARIL (Suspected)	Reason :
Tablet	400 Milligram Daily Oral
Batch :	Started : 01/09/2007 Stopped : 01/11/2007

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0x10 <sup>9</sup> L)	01/09/2007	Pre-treatment 6.8x10 <sup>9</sup> L	
White blood cells	(4.5-11.0x10 <sup>9</sup> L)	01/11/2007	1.30x10 <sup>9</sup> L	
White blood cells	(4.5-11.0x10 <sup>9</sup> L)	03/11/2007	1.10x10 <sup>9</sup> L	
White blood cells	(4.5-11.0x10 <sup>9</sup> L)	04/11/2007	1.00x10 <sup>9</sup> L	
White blood cells	(4.5-11.0x10 <sup>9</sup> L)	05/11/2007	1.60x10 <sup>9</sup> L	
White blood cells	(4.5-11.0x10 <sup>9</sup> L)	06/11/2007	0.80x10 <sup>9</sup> L	
Neutrophils	(1.8-7.7x10 <sup>9</sup> L)	01/09/2007	Pre-treatment 3.9x10 <sup>9</sup> L	
Neutrophils	(1.8-7.7x10 <sup>9</sup> L)	01/11/2007	0.2x10 <sup>9</sup> L	
Neutrophils	(1.8-7.7x10 <sup>9</sup> L)	03/11/2007	0.10x10 <sup>9</sup> L	
Neutrophils	(1.8-7.7x10 <sup>9</sup> L)	04/11/2007	0.10x10 <sup>9</sup> L	
Neutrophils	(1.8-7.7x10 <sup>9</sup> L)	05/11/2007	0.00x10 <sup>9</sup> L	
Neutrophils	(1.8-7.7x10 <sup>9</sup> L)	06/11/2007	0.00x10 <sup>9</sup> L	

## Case Number : 235580

Data Entry Date : 23/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 99

Age :

Onset Date :

DOB : 10/07/1973

Outcome :

Causality : Causality possible

Not yet recovered

**Information:** White cell (WBC) and neutrophil counts (NC) were within normal ranges for the treatment period.  
Has a history of elevated LFTs to other antipsychotic medications (zuclopenthicol).  
At the time of this report the patient had recovered from the episode of AF but the hepatitis remained ongoing.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Atrial fibrillation	Caused or prolonged inpatient hospitalisation	The patient commenced Clopine on 2 August 2007. He developed progressive hepatitis (severe) and experienced an episode of Atrial Fibrillation (moderate).	Metoprolol, initially digoxin. Ceased Clopine.
Hepatitis	Caused or prolonged inpatient hospitalisation		

### Medicine details :

**CLOPINE (Suspected)**

**Reason :** Unspecified schizophrenia

Tablet

150 Milligram

Daily

Oral

**Batch :**

**Started :** 02/08/2007

**Stopped :** 20/08/2007

# Public Case Detail

Cases Count: 393

**Case Number : 235597**

**Data Entry Date :** 23/11/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 24Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Pyrexia	Caused or prolonged inpatient hospitalisation	Pancreatitis, fever and abdominal pain.	Norfloxacin was discontinued.
Abdominal pain	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>METRONIDAZOLE (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>NOROXIN (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 235605**

**Data Entry Date :** 23/11/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 04/10/1983

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Depression		Whilst on Clozaril the patient experienced depression and hypersalivation.	
Salivary hypersecretion			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 14/08/2007	<b>Stopped :</b>	

## Case Number : 235628

Data Entry Date : 26/11/2007

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/11/2007

Age :

DOB : 05/06/1963

Outcome :

Causality : Causality possible

Not yet recovered

### Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutrophil count decreased		On an unspecified date, the patient developed a lung infection for which he had been on Doxilyn and Augmentin Duo Forte during Oct 2007. It was reported that on 5 Nov 2007 whilst on Clozaril 400mg twice daily, blood tests results showed that the patient's white blood cell count was decreased.	

### Medicine details :

<b>AUGMENTIN DUO FORTE (Suspected)</b>	<b>Reason :</b>		
Batch :	Started :	Stopped :	
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	800 Milligram	Daily	Oral
Batch :	Started : 15/04/1994	Stopped :	
<b>DOXYLIN (Suspected)</b>	<b>Reason :</b>		
Batch :	Started :	Stopped :	
<b>EPILIM (Other drug)</b>	<b>Reason :</b>		
Batch :	Started :	Stopped :	

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		09/10/2007	5.90	
White blood cells		05/11/2007	5	
White blood cells		07/11/2007	4.4	
Neutrophils		09/10/2007	3.10	
Neutrophils		07/11/2007	1.4	

# Public Case Detail

Cases Count: 393

**Case Number : 235633**

**Data Entry Date :** 26/11/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 01/08/1979

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Neutrophil count decreased		Patient's neutrophil count decreased.	Ceased Clozaril.

**Medicine details :**

<b>CIPROFLOXACIN (Suspected)</b>		<b>Reason :</b>	
		1 Dose Unspec Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	250 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started : 20/01/2003</b>	<b>Stopped : 08/11/2007</b>	

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
White blood cells		08/10/2007	5.20	
White blood cells		08/11/2007	3.90	
Neutrophils		08/10/2007	2.80	
Neutrophils		08/11/2007	1.20	

## Case Number : 235678

Data Entry Date : 26/11/2007

Gender : M

Hospitalisation : Required a visit to the doctor

Weight (kg) : 0

Onset Date : 08/10/2007

Age :

DOB : 16/08/1969

Outcome :  
Recovered

Causality : Causality probable

### Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Neutropenia	Life threatening	Patient experienced a fall in his white cell count and neutrophil count.	Clozapine ceased.
Leukopenia	Life threatening		

### Medicine details :

**CLOZARIL (Suspected)** Reason : Agranulocytosis

Tablet 250 Milligram Daily Oral

Batch : Started : 12/04/2007 Stopped : 08/10/2007

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells	(4.0-11.0)	08/10/2007	3.5	
White blood cells	(4.0-11.0)	15/10/2007	2.6	
White blood cells	(4.0-11.0)	22/10/2007	2.7	
White blood cells	(4.0-11.0)	02/11/2007	7.1	
Neutrophils	(2.0-8.0)	08/10/2007	1.5	
Neutrophils	(2.0-8.0)	15/10/2007	1.2	
Neutrophils	(2.0-8.0)	20/10/2007	2.7	
Neutrophils	(2.0-8.0)	02/11/2007	3.7	

# Public Case Detail

Cases Count: 393

**Case Number : 235684**

**Data Entry Date :** 27/11/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 22/09/2007

**Age :**

**DOB :** 27/07/1981

**Outcome :** 22/09/2007

**Causality :** Causality possible

Death

**Information:** FI provides history of increased suicidal ideation and uncontrolled schizophrenia. Patient confirmed to have been on clozapine, mirtazapine and ranitidine at time of death, but some doubts about compliance have been raised.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Completed suicide	Death	Patient completed suicide by hanging.	

## Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	225 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 04/10/2006	<b>Stopped :</b> 22/09/2007	



# Public Case Detail

Cases Count: 393

**Case Number : 235748**

**Data Entry Date :** 28/11/2007

**Gender :** M

**Hospitalisation :** Required a visit to the doctor

**Weight (kg) :** 0

**Onset Date :** 25/10/2007

**Age :**

**DOB :** 20/12/1983

**Outcome :**  
Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Pancreatitis acute	Caused or prolonged inpatient hospitalisation	Acute pancreatitis, abdominal pain and fever. Lipase and amylase levels increased. Gastroenteritis.	Clozaril ceased by patient and re-initiated on Clozaril slowly.
Abdominal pain	Caused or prolonged inpatient hospitalisation		
Blood amylase increased	Caused or prolonged inpatient hospitalisation		
Diarrhoea	Caused or prolonged inpatient hospitalisation		
Gastroenteritis	Caused or prolonged inpatient hospitalisation		
Lipase increased	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	125 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 11/10/2007	<b>Stopped :</b>	
<b>FLAGYL (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>NOROXIN (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
lipase				Lipase and amylase levels were 'very high'

## Case Number : 235820

**Data Entry Date :** 03/12/2007  
**Hospitalisation :** Admitted to hospital  
**Onset Date :**  
**Outcome :** 25/09/2007  
 Death

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 15/10/1954  
**Causality :** Causality possible

**Information:** The death was sudden and of unknown cause at the time of the report.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism	Death	Patient experienced pulmonary embolism, sudden death, neuroleptic malignant syndrome, blood creatine phosphokinase increased, antipsychotic drug level increased.	
Antipsychotic drug level increased	Death		
Blood creatine phosphokinase increased	Death		
Neuroleptic malignant syndrome	Death		
Sudden death	Death		

### Medicine details :

<b>Abilify (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
Tablet	15 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/02/2007	<b>Stopped :</b>	
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
Tablet	500 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 25/10/1993	<b>Stopped :</b> 25/09/2007	

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		15/09/2007	933	
Creatine phosphokinase		25/09/2007	2216	
White blood cells		15/09/2007	19	
Serum drug level				10 Nov 2005 Serm clozapine: 574ug/L (on Clozaril dose of 250mg bd)

# Public Case Detail

Cases Count: 393

**Case Number : 236050**

**Data Entry Date :** 07/12/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 20/10/2007

**Age :**

**DOB :** 18/04/1973

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** Treatment with Clopine is continuing.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Subdural haematoma	Caused or prolonged inpatient hospitalisation	Patient experienced subdural haematoma, confusion and headache whilst on Clopine.	ICU. Epilim was ceased. Phenytoin. Craniotomy was performed.
Confusional state	Caused or prolonged inpatient hospitalisation		
Headache	Caused or prolonged inpatient hospitalisation		

## Medicine details :

<b>ASPIRIN (Suspected)</b>		<b>Reason :</b> Headache	
		Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0
<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	Contin
<b>EPILIM (Suspected)</b>		<b>Reason :</b> Other&unspecified epilepsy	
		600 Milligram Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0
<b>CLOMIPRAMINE HYDROCHLORIDE (Other drug)</b>		<b>Reason :</b>	
Tablet	150 Milligram		Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells				Patient's white blood cell counts were within normal ranges for the treatment period, with the exception of a few slightly raised counts.
Neutrophils				Patient's neutrophill counts were within normal ranges for the treatment period, with the exception of a few slightly raised counts.

# Public Case Detail

Cases Count: 393

**Case Number : 236119**

**Data Entry Date :** 11/12/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 16/07/1973

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Patient experienced flu-like symptoms, a fever (39 C), generally felt unwell, had vague chest pain and troponin level of 0.1.	
Chest pain			
Malaise			
Pyrexia			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	225 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 26/10/2007	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
White blood cells				Patient's white blood cell count have remained within normal ranges over the duration of treatment.
Neutrophils				Patient's neutrophil count have remained within normal ranges form the duration of treatment.t

# Public Case Detail

Cases Count: 393

**Case Number : 236124**

**Data Entry Date :** 11/12/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 04/01/2007

**Age :**

**DOB :** 09/03/1972

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Neutropenia		Patient experienced Neutropenia.	Clozapine ceased.

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 26/10/1998	<b>Stopped :</b> 05/10/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 236369**

**Data Entry Date :** 17/12/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 21/11/2007

**Age :**

**Outcome :** 21/11/2007

**DOB :** 28/11/1958

Death

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Acute myocardial infarction	Death	Patient died as a result of an acute myocardial infarction whilst being treated with Clopine.	

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	500 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 08/08/2006 <b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 236386**

**Data Entry Date :** 18/12/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 30/10/1970

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Pulmonary embolism	Caused or prolonged inpatient hospitalisation	Patient experienced a pulmonary embolism described as severe in intensity.	ICU. Ceased Clopine.

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	350 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 07/03/2007	<b>Stopped :</b> 30/11/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 236392**

**Data Entry Date :** 18/12/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 75

**Onset Date :** 16/08/2007

**Age :**

**DOB :** 03/07/1981

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Left ventricular dysfunction	Incapacity/disability	Onset of LV global dysfunction	

<b>Medicine details :</b>			
<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Capsule	350 Milligram	1 time	Oral
<b>Batch :</b>	<b>Started :</b> 16/08/2005	<b>Stopped :</b> 16/10/2007	



# Public Case Detail

Cases Count: 393

**Case Number : 236396**

**Data Entry Date :** 18/12/2007

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 28/10/1963

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Hyperthermia malignant	Caused or prolonged inpatient hospitalisation	Patient developed hyperthermia malignant possibly had an infection.	Discontinuation of Clozaril.
Infection	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 07/11/2007	<b>Stopped :</b> 23/11/2007	

## Case Number : 236454

Data Entry Date : 20/12/2007

Gender : M

Hospitalisation :

Weight (kg) : 91

Onset Date : 10/11/2007

Age : 34Y

Outcome :

DOB :

Unknown

Causality : Causality possible

### Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Left ventricular dysfunction		Left ventricular dysfunction. Intermittent breathlessness and chest pain on exertion now resolved with cessation of clozapine.	Cessation of clozapine.
Cardiomyopathy			
Chest pain			
Dyspnoea			

### Medicine details :

<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	500 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 27/08/2007	<b>Stopped :</b> 12/12/2007	
<b>CLOPIXOL (Other drug)</b>		<b>Reason :</b>	
Injection	150 Milligram	Intramuscular	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				Echocardiogram result 10/11- Left ventricular dysfunction. Mild to moderate symmetrical or global hypokinesia with his fractional shortening being reduced to 24%. This equates to an ejection of around 44-48%.

# Public Case Detail

Cases Count: 393

**Case Number : 236510**

**Data Entry Date :** 24/12/2007

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 04/01/1979

**Outcome :**

**Causality :** Causality possible

Unrelated death

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Death	Death	Patient commenced treatment with clozapine and switched to Clopine on 21 Nov 2006. Patient was titrated up to a maximum dose of 1050g/PO daily. Prior to the patient's death he was on a stable dose of 675mg/PO daily.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	675 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 20/08/1998	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 236770**

**Data Entry Date :** 08/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 19/07/1957

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocardial infarction		The patient experienced a heart attack and Ischaemic Heart Disease.	Ceased Clopine
Myocardial ischaemia			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	225 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 30/10/2007	<b>Stopped :</b> 16/11/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 236789**

**Data Entry Date :** 09/01/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 03/01/1970

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Cardiomyopathy		Patient developed cardiomyopathy whilst on Clozaril.	Clozaril ceased.

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 12/09/1997	<b>Stopped :</b> 26/11/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 236791**

**Data Entry Date :** 09/01/2008

**Gender :** M

**Hospitalisation :** Treated in Accident/Emergency Depar

**Weight (kg) :** 0

**Onset Date :** 29/11/2007

**Age :**

**DOB :** 21/04/1976

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:** Current condition: Arthropode bit on neck.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Somnolence		The patient then experienced drowsiness. On examination he was stable, but was tachycardic (136bpm in triage).	
Tachycardia			

## Medicine details :

CLOZARIL (Suspected)	Reason :
Tablet	400 Milligram 1 time Oral
<b>Batch :</b>	<b>Started :</b> 29/11/2007 <b>Stopped :</b>

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Blood pressure		30/11/2007	136bpm.	Tachycardic

# Public Case Detail

Cases Count: 393

**Case Number : 236809**

**Data Entry Date :** 09/01/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 07/05/2007

**Age :**

**DOB :** 23/12/1952

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased		On 7 May 2007 whilst on Clozaril, the patient's while blood cells and neutrophil counts were measured low. Clozaril was withheld for one day and resumed with no change. Valproate sodium was added and Clozaril dose increased. On 25 Oct 07 the patient had low blood counts again. Clozaril was discontinued with immediate positive result. The patient had then a severe rebound psychosis, became uncooperative and catatonic at times. She stopped eating and drinking and became dehydrated, despite reasonable doses of typical anti-psychotics intramuscularly.	
Neutrophil count decreased			

**Medicine details :**

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	400 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 21/03/2006 <b>Stopped :</b> 25/10/2007 0
<b>SODIUM VALPROATE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0)	16/03/2006	8.80	
White blood cells	(4.5-11.0)	25/10/2007	3.20	
White blood cells	(4.5-11.0)	31/10/2007	4.90	

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0)	20/11/2007	3.50	
Neutrophils	(1.8-7.7)	16/03/2006	6.24	
Neutrophils	(1.8-7.7)	25/10/2007	1.40	
Neutrophils	(1.8-7.7)	20/11/2007	1.90	



# Public Case Detail

Cases Count: 393

**Case Number : 236822**

**Data Entry Date :** 09/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 20/11/2007

**Age :**

**Outcome :** 20/11/2007

**DOB :** 16/02/1971

Death

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Death	Death	Male patient died due to unknown reasons whilst being treated with Clopine.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	900 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 10/05/2005	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 236824**

**Data Entry Date :** 09/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/10/2007

**Age :**

**DOB :** 13/06/1979

**Outcome :** 15/10/2007

**Causality :** Causality possible

Death

**Information:** FI suggests possible intentional overdose because several packets of clozapine found near patient, but overdose is unconfirmed

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient died due to unknown reasons whilst being treated with Clopine.	

## Medicine details :

<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 236825**

**Data Entry Date :** 09/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 01/12/2007

**Age :**

**DOB :** 23/10/1956

**Outcome :** 01/12/2007

**Causality :** Causality possible

Death

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Death	Death	Patient died due to unknown reasons whilst being treated with Clopine.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 05/05/2007	<b>Stopped :</b> 01/12/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 236872**

**Data Entry Date :** 10/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 14/12/1972

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Sinus tachycardia		Patient developed tachycardia.	
Echocardiogram abnormal			
Electrocardiogram abnormal			
Pericardial effusion			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	500 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 12/09/2007	<b>Stopped :</b>	
<b>AMISULPRIDE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Other data				Tachycardia:110-130 bpm.
Electrocardiography				Tachycardia ranging 115-138 bpm.

## Case Number : 236909

Data Entry Date : 11/01/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 30/06/2006

Age :

DOB : 20/11/1980

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Heart rate irregular		Patient developed parotid swelling, mild tonsillar erythema, vomiting, productive cough, raised monocytes, sinus tachycardia, palpitations at times, ventricular bigeminy, macular facial and chest rash.	Ceased Clozapine
Palpitations			
Parotid gland enlargement			
Productive cough			
Rash macular			
Sinus bradycardia			
Tonsillar disorder			
Ventricular extrasystoles			
Vomiting			

#### Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 236944**

**Data Entry Date :** 14/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/11/2007

**Age :**

**DOB :** 29/06/1948

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome		Patient experienced delirium, hypersalivation, altered mental state and fever.	Ceased Clozapine
Delirium			
Mental status changes			
Pyrexia			
Salivary hypersecretion			

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
Tablet	200 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 12/11/2007 <b>Stopped :</b> 30/11/2007

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
White blood cells				White blood cells were within normal ranges.
Neutrophils				Neutrophil counts were within normal ranges throughout treatment.

# Public Case Detail

Cases Count: 393

**Case Number : 236971**

**Data Entry Date :** 15/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 20/12/1968

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** Patient's white blood cell counts (WCC) and neutrophil counts (NC) were within normal ranges for the treatment period.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient had early stage cardiomyopathy and ventricular dilatation.	Ceased Clopine
Dilatation ventricular			

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
Tablet	500 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 20/02/2007 <b>Stopped :</b> 04/12/2007

## Case Number : 237151

Data Entry Date : 21/01/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 18/12/2007

Age :

DOB : 20/07/1948

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced neutropenia and leukopenia.	Ceased Clozaril.
Leukopenia			

#### Medicine details :

CLOZARIL (Suspected)	Reason :
Tablet	500 Milligram Daily Oral
Batch :	Started : 15/04/1994 Stopped : 04/12/2007

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	15/08/1994	4.6x10 <sup>9</sup> /L (pre-treatment)	
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	29/11/2007	5.50x10 <sup>9</sup> /L	
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	04/12/2007	2.60x10 <sup>9</sup> /L	
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	05/12/2007	2.20x10 <sup>9</sup> /L	
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	07/12/2007	2.30x10 <sup>9</sup> /L	
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	10/12/2007	2.00x10 <sup>9</sup> /L	
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	12/12/2007	1.70x10 <sup>9</sup> /L	
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	13/12/2007	1.20x10 <sup>9</sup> /L	
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	18/12/2007	1.0 x 10 <sup>9</sup> /L	
Neutrophils	(1.8-11.0x10 <sup>9</sup> /L)	15/08/1994	2.8x10 <sup>9</sup> /L (pre-treatment)	
Neutrophils	(1.8-11.0x10 <sup>9</sup> /L)	29/11/2007	4.20x10 <sup>9</sup> /L	
Neutrophils	(1.8-11.0x10 <sup>9</sup> /L)	04/12/2007	1.70x10 <sup>9</sup> /L	
Neutrophils	(1.8-11.0x10 <sup>9</sup> /L)	05/12/2007	1.30x10 <sup>9</sup> /L	
Neutrophils	(1.8-11.0x10 <sup>9</sup> /L)	07/12/2007	1.00x10 <sup>9</sup> /L	
Neutrophils	(1.8-11.0x10 <sup>9</sup> /L)	10/12/2007	0.70x10 <sup>9</sup> /L	
Neutrophils	(1.8-11.0x10 <sup>9</sup> /L)	12/12/2007	0.20x10 <sup>9</sup> /L	
Neutrophils	(1.8-11.0x10 <sup>9</sup> /L)	13/12/2007	0.10x10 <sup>9</sup> /L	
Neutrophils	(1.8-11.0x10 <sup>9</sup> /L)	18/12/2007	0.1 x 10 <sup>9</sup> /L	



# Public Case Detail

Cases Count: 393

**Case Number : 237206**

**Data Entry Date :** 22/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 01/01/1978

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Patient was described as having chest pain, breathlessness, muscle aches, tachycardia, increased creatine kinase and suspected myocarditis.	Clozapine ceased.
Blood creatine phosphokinase increased			
Chest pain			
Dyspnoea			
Myalgia			
Tachycardia			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 28/05/2007	<b>Stopped :</b> 15/12/2007	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Heart Rate				Parameter: Heart rate: Value = 100-120
Creatine phosphokinase				Parameter: Creatine kinase: Value = 500

# Public Case Detail

Cases Count: 393

**Case Number : 237211**

**Data Entry Date :** 22/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 16/03/1980

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Cardiomyopathy		Patient developed cardiomyopathy.	Clozaril discontinued.

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	25 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 03/08/2004	<b>Stopped :</b>	10/12/2007

# Public Case Detail

Cases Count: 393

**Case Number : 237215**

**Data Entry Date :** 22/01/2008

**Gender :** M

**Hospitalisation :** Treated in Accident/Emergency Depar

**Weight (kg) :** 0

**Onset Date :** 27/06/2003

**Age :**

**DOB :** 24/05/1963

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** Historical drug: mood stabilizer without effect.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased	Caused or prolonged inpatient hospitalisation	Patient's white blood cell count decreased and his neutrophil count decreased.	Clozaril discontinued.
Neutrophil count decreased	Caused or prolonged inpatient hospitalisation		

## Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	800 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 05/10/1993	<b>Stopped :</b> 24/06/2003	0

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		12/05/2003	3.80 x 10 <sup>9</sup> /L	
White blood cells		27/06/2003	2.80 x 10 <sup>9</sup> /L	
White blood cells		04/08/2003	13.20 x 10 <sup>9</sup> /L	
Neutrophils		12/05/2003	1.70 x 10 <sup>9</sup> /L	
Neutrophils		27/06/2003	1.00 x 10 <sup>9</sup> /L	
Neutrophils		04/08/2003	9.10 x 10 <sup>9</sup> /L	

# Public Case Detail

Cases Count: 393

**Case Number : 237388**

**Data Entry Date :** 29/01/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 22/05/1976

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** The treating psychiatrist reported two possible causes of NMS. The first was that the NMS was directly caused by Clopine treatment. The second was hyponatremia caused by venlafaxine and desmopressin, led to seizures which was treated with haloperidol. This chain of events led to NMS.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Patient commenced treatment with Clopine on 26 March 2007. Patient developed neuroleptic malignant syndrome and 'pseudo pneumonia' (pneumonia due to pseudomonas).	
Convulsion	Caused or prolonged inpatient hospitalisation		
Lung infection pseudomonal	Caused or prolonged inpatient hospitalisation		

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>	
Tablet	450 Milligram	Daily
		Oral
<b>Batch :</b>	<b>Started :</b> 26/03/2007	<b>Stopped :</b> 06/01/2008

# Public Case Detail

Cases Count: 393

**Case Number : 237399**

**Data Entry Date :** 29/01/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**Outcome :**

**DOB :** 31/01/1982

Recovered

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Weight increased	Incapacity/disability	Patient gained 10kg (from 73kg to 83.8kg).	Clozaril discontinued, dietician and exercise for weight control.

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	75 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 28/04/2003	<b>Stopped :</b> 14/11/2007	

# Public Case Detail

Cases Count: 393

**Case Number : 237482**

**Data Entry Date :** 01/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 10/11/2007

**Age :**

**DOB :** 19/09/1973

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:** Cardiologists recommendation who believed the findings were secondary to clozapine.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Left ventricular dysfunction		Left ventricular dysfunction, ejection fraction decreased, echocardiogram abnormal, chest pain, shortness of breath.	Ceased Clozaril
Chest pain			
Dyspnoea			
Echocardiogram abnormal			
Ejection fraction decreased			

## Medicine details :

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	600 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 28/08/2007 <b>Stopped :</b> 12/12/2007
<b>CLOPIXOL (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				Echo: left ventricular dysfunction, ejection fraction 44-48%. No baseline echocardiogram was performed prior to the start of Clozaril treatment.

## Case Number : 237502

Data Entry Date : 04/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 07/12/2007

Age :

DOB : 22/06/1959

Outcome :

Causality : Causality possible

Recovered

**Information:** White blood cell (WBC) and neutrophil counts (NC) were within normal ranges for the treatment period.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		Patient experienced a severe tonic-clonic seizure lasting approximately 3 minutes including myoclonic activity and loss of consciousness. She had another complex partial seizure in the right side of her face lasting approximately 2 minutes.	Clopine ceased
Complex partial seizures			

### Medicine details :

<b>AMISULPRIDE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	800 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 01/10/2007	<b>Stopped :</b>	
<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	750 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 05/09/2007	<b>Stopped :</b> 19/12/2007	0
<b>ASPIRIN (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>ATORVASTATIN (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>CHLORPROMAZINE HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>OMEPRAZOLE (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>SODIUM VALPROATE (Other drug)</b>	<b>Reason :</b> Unspecified psychosis		
	2.2 Gram	Daily	
<b>Batch :</b>	<b>Started :</b> 01/10/2007	<b>Stopped :</b>	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level				The patient was noted to a clozapine level of 660.
Haemoglobin				HB 107



# Public Case Detail

Cases Count: 393

**Case Number : 237507**

**Data Entry Date :** 04/02/2008

**Gender :** M

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Onset Date :** 20/12/2007

**Age :**

**Outcome :** 02/01/2008

**DOB :** 27/03/1974

Recovered

**Causality :** Causality possible

**Information:** Ref number 18147 linked with 19398.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation	Patient was noted as having an increase in creatine phosphokinase levels. He also developed GI disturbances and a fever, up to 39.8 degrees celsius. He also developed orthostatic hypotension.	Ceased treatment with Clopine.
Gastrointestinal disorder	Caused or prolonged inpatient hospitalisation		
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
Tablet	200 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 11/12/2007 <b>S TERM</b> <b>Stopped :</b> 24/12/2007

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine kinase MB				01 Dec 2007: up to 18000

## Case Number : 237510

Data Entry Date : 04/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 112

Onset Date : 08/10/2007

Age :

Outcome : 12/11/2007

DOB : 10/01/1973

Recovered

Causality : Causality possible

**Information:** A smoker and has a history of alcohol abuse. Patient's mother had a myocardial infarction aged 50.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient ceased treatment with Clopine due to myocarditis.	Cessation of Clopine.
Chest pain			
Dyspnoea			
Ejection fraction decreased			

### Medicine details :

<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Schizo-affective type psychos	
Tablet	250 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 20/09/2007	<b>Stopped :</b> 09/10/2007	0
<b>RISPERIDONE (Other drug)</b>		<b>Reason :</b>	
	4 Milligram		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>SERTRALINE HYDROCHLORIDE (Other drug)</b>		<b>Reason :</b>	
	50 Milligram		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>SODIUM VALPROATE (Other drug)</b>		<b>Reason :</b>	
	750 Milligram		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Ejection fraction		08/10/2007	72%	
Ejection fraction		15/10/2007	47%	
Ejection fraction		15/12/2007	67%	

# Public Case Detail

Cases Count: 393

**Case Number : 237543**

**Data Entry Date :** 04/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99U

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Retrograde ejaculation		The reporter informed that the patient developed retrograde ejaculation during therapy with Clozaril.	

<b>Medicine details :</b>	
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Prolactin				Normal result

# Public Case Detail

Cases Count: 393

**Case Number : 237560**

**Data Entry Date :** 04/02/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 02/01/2008  
**Outcome :**  
 Not yet recovered

**Gender :** F  
**Weight (kg) :** 55  
**Age :**  
**DOB :** 23/08/1967  
**Causality :** Causality possible

**Information:** The patient has had a poor response to many antipsychotics and has tardive dyskinesia (details not provided). No other relevant medical history, if any, was reported.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Life threatening	Severe neutropenia and severe leucopenia.	Clopine ceased.
Leukopenia	Life threatening		
Pharyngitis	Life threatening		

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 11/03/2004	<b>L TERM</b>	<b>Stopped :</b> 02/01/2008

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		04/01/2008	0.60	X10^9/L
White blood cells		03/01/2008	0.50	X10^9/L
White blood cells		02/01/2008	0.50	X10^9/L
White blood cells		03/12/2007	5.30	X10^9/L
Neutrophils		04/01/2008	0.00	(X10^9/L)
Neutrophils		03/01/2008	0.00	(X10^9/L)
Neutrophils		02/01/2008	0.00	(X10^9/L)
Neutrophils		03/12/2007	3.30	(X10^9/L)
Serum drug level	(MG/DAY)	04/01/2008	0.0	Clozapine
Serum drug level	(MG/DAY)	03/01/2008	0.0	Clozapine
Serum drug level	(MG/DAY)	02/01/2008	0.0	Clozapine
Serum drug level	(MG/DAY)	03/12/2007	400.0	Clozapine

# Public Case Detail

Cases Count: 393

**Case Number : 237561**

**Data Entry Date :** 04/02/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/12/2007

**Age :**

**DOB :** 23/10/1967

**Outcome :**

**Causality :** Causality probable

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Troponin increased	Life threatening	Patient experienced increased troponin whilst on Clopine treatment.	Clopine ceased.

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	275 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 06/12/2007	<b>Stopped :</b> 24/12/2007	0

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Troponin				Dec 2007: 0.38 (Elevated)

# Public Case Detail

Cases Count: 393

**Case Number : 237565**

**Data Entry Date :** 04/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/01/2008

**Age :**

**DOB :** 21/05/1952

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Leukopenia	Life threatening	Patient's routine blood tests revealed severe neutropenia (grade 4) and severe leucopenia (grade 3).	Ceased Clopine.
Agranulocytosis	Life threatening		

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
Tablet	100 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 22/11/2007 <b>S TERM</b> <b>Stopped :</b> 15/01/2008

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
White blood cells		16/01/2008	1.90	(x10 <sup>9</sup> /L)
White blood cells		15/01/2008	1.80	(x10 <sup>9</sup> /L)
White blood cells		08/01/2008	4.60	(x10 <sup>9</sup> /L)
Neutrophils		16/01/2008	0.10	(X10 <sup>9</sup> /L)
Neutrophils		15/01/2008	0.10	(X10 <sup>9</sup> /L)
Neutrophils		08/01/2008	3.30	(X10 <sup>9</sup> /L)
Serum drug level		16/01/2008	0.0	Dose (MG)
Serum drug level		15/01/2008	0.0	Dose (MG)
Serum drug level		08/01/2008	100.0	Dose (MG)

## Case Number : 237576

Data Entry Date : 05/02/2008

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 05/11/2007

Age : 41Y

Outcome :

DOB :

Recovered

Causality : Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug level increased	Caused or prolonged inpatient hospitalisation	Patient stable on Clozapine but had multiple seizures. These are now thought to coincide with his attempts to quit smoking (reduced from 40 to 20 /day).	Clozapine withheld.
Convulsion	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

Medicine	Reason :
<b>Cigarettes (Interaction)</b>	
Batch :	Started : L TERM Stopped : 0
<b>CLOZARIL (Interaction)</b>	
Tablet	750 Milligram Daily Oral
Batch :	Started : L TERM Stopped : 0
<b>DITROPAN (Other drug)</b>	
	10 Milligram Daily Oral
Batch :	Started : Stopped :
<b>TOFRANIL (Other drug)</b>	
	25 Milligram Daily
Batch :	Started : Stopped :
<b>VALPRO (Other drug)</b>	
Tablet	2 Gram Daily Oral
Batch :	Started : Stopped :

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level				On admission, clozapine level was 1800.

# Public Case Detail

Cases Count: 393

**Case Number : 237577**

**Data Entry Date :** 05/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 09/05/1976

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Possible myocarditis, pericardial effusion and tachycardia.	
Pericardial effusion			
Tachycardia			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	500 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 21/02/2007	<b>Stopped :</b> 14/01/2008	0



## Case Number : 237793

Data Entry Date : 11/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 29/04/2005

Age :

DOB : 03/10/1980

Outcome :

Causality : Causality possible

Not yet recovered

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased		Low neutrophil count and white blood cell count.	Cessation of Clozaril.
Antipsychotic drug level increased			
Neutrophil count decreased			

#### Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	475 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 27/08/2003	<b>Stopped :</b> 08/06/2005	
<b>EPILIM (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		01/12/2004	3.70	8.10x10 <sup>9</sup> /L pre-treatment
White blood cells		03/06/2005	3.40	8.10x10 <sup>9</sup> /L pre-treatment
White blood cells		05/07/2005	6.20	8.10x10 <sup>9</sup> /L pre-treatment
Neutrophils		01/12/2004	2.10	5.80x10 <sup>9</sup> /L pre treatment
Neutrophils		03/06/2005	1.30	5.80x10 <sup>9</sup> /L pre treatment
Neutrophils		05/07/2005	3.30	5.80x10 <sup>9</sup> /L pre treatment
Other data		29/04/2005	1080 mcg/L	Serum clozapine
Other data		09/06/2005	50 mcg/L	Serum clozapine

# Public Case Detail

Cases Count: 393

## Case Number : 237798

Data Entry Date : 11/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 15/06/1981

Outcome :

Causality : Causality possible

Unknown

**Information:** Medical History: Alcoholism/ drug abuser. The nurse informed that stutter started as soon as the patient was stated on Clozaril and patient's family had verified he did not have stutter before Clozaril.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Dysphemia		Patient experienced stutter and twitch on his face, as well as weight gain.	
Facial spasm			
Weight increased			

### Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	500 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 17/07/2006	<b>Stopped :</b>	

## Case Number : 237799

Data Entry Date : 11/02/2008

Hospitalisation :

Onset Date :

Outcome :

Unknown

Gender : M

Weight (kg) : 0

Age :

DOB : 31/07/1977

Causality : Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Ventricular hypokinesia		A "recent" echocardiography showed that the patient's inferoseptum and inferior wall were mildly hypokinetic. The echocardiography also showed mild septal hypertrophy and right ventricular dilatation.	Metoprolol.
Dilatation ventricular			
Echocardiogram abnormal			
Hypertension			
Tachycardia			
Type 2 diabetes mellitus			
Ventricular hypertrophy			

#### Medicine details :

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	500 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 19/09/2005 <b>Stopped :</b>
<b>CITALOPRAM HYDROBROMIDE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 237807**

**Data Entry Date :** 11/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 17/01/2008

**Age :**

**DOB :** 19/11/1977

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** the physician advised that the patient had always had a low neutrophil count even before starting Clozaril, these levels fluctuated over the first 12 months.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
White blood cell count decreased		Patient's blood tests showed low neutrophil and white blood cell count.	Ceased Clozaril.
Neutrophil count decreased			

## Medicine details :

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	450 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 11/01/2007	<b>Stopped :</b> 17/01/2008	0

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		17/01/2008	3.7	Pretreatment 5.9
White blood cells		07/02/2008	4.1	Pretreatment 5.9
Neutrophils		17/01/2008	1.4	pre-treatment 3.5
Neutrophils		07/02/2008	1.9	pre-treatment 3.5

**Case Number : 237841**

**Data Entry Date :** 12/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 22/01/2008

**Age :**

**DOB :** 10/09/1982

**Outcome :**

**Causality :** Causality probable

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Caused or prolonged inpatient hospitalisation	Agranulocytosis	Ceased Clozaril

**Medicine details :**

CLOZARIL (Suspected)	Reason :
Tablet	300 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 04/12/2007 <b>Stopped :</b> 21/01/2008

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0)	24/11/2007	5.8	
White blood cells	(4.5-11.0)	04/12/2007	5.80	
White blood cells	(4.5-11.0)	14/01/2008	3.90	
White blood cells	(4.5-11.0)	21/01/2008	2.10	
White blood cells	(4.5-11.0)	22/01/2008	2.00	
White blood cells	(4.5-11.0)	23/01/2008	2.90	
Neutrophils	(1.8-7.7)	24/11/2007	3.23	
Neutrophils	(1.8-7.7)	04/12/2007	3.23	
Neutrophils	(1.8-7.7)	14/01/2008	2.30	
Neutrophils	(1.8-7.7)	21/01/2008	0.63	
Neutrophils	(1.8-7.7)	22/01/2008	0.30	
Neutrophils	(1.8-7.7)	23/01/2008	0.009	

# Public Case Detail

Cases Count: 393

**Case Number : 237842**

**Data Entry Date :** 12/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 19/01/2008

**Age :**

**DOB :** 04/08/1957

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Deep vein thrombosis	Caused or prolonged inpatient hospitalisation	Patient developed deep vein thrombosis.	

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	750 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 17/05/1993	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Ultrasound				DVT confirmed at hospital by ultrasound.

# Public Case Detail

Cases Count: 393

**Case Number : 237846**

**Data Entry Date :** 12/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 18/01/2008

**Age :**

**DOB :** 23/03/1951

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Neutropenia		Patient experienced decreased White blood cell count.	Clozaril was discontinued.
White blood cell count decreased			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	700 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 01/06/1997	<b>Stopped :</b> 18/01/2008	0

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		18/01/2008	2.30	
White blood cells		18/02/2008	4.3	
Neutrophils		18/01/2008	1.10	
Neutrophils		18/02/2008	2.6	

# Public Case Detail

Cases Count: 393

**Case Number : 237994**

**Data Entry Date :** 18/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 03/01/1956

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Cardiac disorder	Caused or prolonged inpatient hospitalisation	Cardiac complications.	Ceased Clopine

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 20/12/2006	<b>Stopped :</b>	



## Case Number : 238008

Data Entry Date : 18/02/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/11/2007

Age : 37Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Left ventricular dysfunction	Caused or prolonged inpatient hospitalisation	LV dysfunction (on TTE), LV wall thickened and reduction in ejection traction.	
Cardiac hypertrophy	Caused or prolonged inpatient hospitalisation		
Ejection fraction decreased	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

<b>CLOZAPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	300 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>ATROPINE (Other drug)</b>	<b>Reason :</b>
	3 Dose Unspec Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>COGENTIN (Other drug)</b>	<b>Reason :</b>
	0.5 Milligram
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>DIAZEPAM (Other drug)</b>	<b>Reason :</b>
	2 Milligram
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>Microgynon 50 ED (Other drug)</b>	<b>Reason :</b>
	1
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				gated blood pool: EF 54%

## Case Number : 238102

Data Entry Date : 20/02/2008

Gender : F

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 15/01/2008

Age :

Outcome :

DOB : 22/04/1953

Unknown

Causality : Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis	Caused or prolonged inpatient hospitalisation	Patient commenced on Clozaril on the 16/12/07 and on the 29/01/08, the patient's blood test results showed decreased white blood cells and neutrophils counts. Patient was afebrile and developed neutropenic fever, without clear source of infection.	Clozaril ceased the same day. Patient switched to aripiprazole on 01/02/08. Treated with IV tazocin and Granulocyte Colony Stimulating Factor (GCSF).
Anaemia	Caused or prolonged inpatient hospitalisation		
Febrile neutropenia	Caused or prolonged inpatient hospitalisation		
Neutrophil count decreased	Caused or prolonged inpatient hospitalisation		
White blood cell count decreased	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>
Tablet	350 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 16/12/2007 <b>Stopped :</b> 29/01/2008
<b>EFEXOR (Other drug)</b>	<b>Reason :</b>
Tablet	Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	29/01/2008	1.90	Pre treatment WBC = 9.2x10 <sup>9</sup> /L
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	30/01/2008	0.90	Pre treatment WBC = 9.2x10 <sup>9</sup> /L
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	31/01/2008	0.70	Pre treatment WBC = 9.2x10 <sup>9</sup> /L
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	02/02/2008	1.30	Pre treatment WBC = 9.2x10 <sup>9</sup> /L

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	04/02/2008	0.70	Pre treatment WBC = 9.2x10 <sup>9</sup> /L
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	05/02/2008	0.90	Pre treatment WBC = 9.2x10 <sup>9</sup> /L
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	07/02/2008	1.50	Pre treatment WBC = 9.2x10 <sup>9</sup> /L
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	08/02/2008	0.90	Pre treatment WBC = 9.2x10 <sup>9</sup> /L
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	09/02/2008	0.80	Pre treatment WBC = 9.2x10 <sup>9</sup> /L
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	10/02/2008	1.20	Pre treatment WBC = 9.2x10 <sup>9</sup> /L
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	11/02/2008	4.00	Pre treatment WBC = 9.2x10 <sup>9</sup> /L
White blood cells	(4.5-11.0x10 <sup>9</sup> /L)	26/02/2008	7.4	Pre treatment WBC = 9.2x10 <sup>9</sup> /L
Neutrophils	(1.8-7.7x10 <sup>9</sup> /L)	29/01/2008	1.10	Pre treatment neut count = 9.2x10 <sup>9</sup> /L
Neutrophils	(1.8-7.7x10 <sup>9</sup> /L)	30/01/2008	0.40	Pre treatment neut count = 9.2x10 <sup>9</sup> /L
Neutrophils	(1.8-7.7x10 <sup>9</sup> /L)	31/01/2008	0.00	Pre treatment neut count = 9.2x10 <sup>9</sup> /L
Neutrophils	(1.8-7.7x10 <sup>9</sup> /L)	02/02/2008	0.10	Pre treatment neut count = 9.2x10 <sup>9</sup> /L
Neutrophils	(1.8-7.7x10 <sup>9</sup> /L)	04/02/2008	0.00	Pre treatment neut count = 9.2x10 <sup>9</sup> /L
Neutrophils	(1.8-7.7x10 <sup>9</sup> /L)	05/02/2008	0.00	Pre treatment neut count = 9.2x10 <sup>9</sup> /L
Neutrophils	(1.8-7.7x10 <sup>9</sup> /L)	07/02/2008	0.00	Pre treatment neut count = 9.2x10 <sup>9</sup> /L
Neutrophils	(1.8-7.7x10 <sup>9</sup> /L)	08/02/2008	0.00	Pre treatment neut count = 9.2x10 <sup>9</sup> /L
Neutrophils	(1.8-7.7x10 <sup>9</sup> /L)	09/02/2008	0.00	Pre treatment neut count = 9.2x10 <sup>9</sup> /L
Neutrophils	(1.8-7.7x10 <sup>9</sup> /L)	10/02/2008	0.10	Pre treatment neut count = 9.2x10 <sup>9</sup> /L
Neutrophils	(1.8-7.7x10 <sup>9</sup> /L)	11/02/2008	2.40	Pre treatment neut count = 9.2x10 <sup>9</sup> /L
Neutrophils	(1.8-7.7x10 <sup>9</sup> /L)	26/02/2008	5.0	Pre treatment neut count = 9.2x10 <sup>9</sup> /L
Haemoglobin		26/02/2008	107	Hb = 112 (mild anaemia).

# Public Case Detail

Cases Count: 393

**Case Number : 238113**

**Data Entry Date :** 20/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 31/05/1966

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Pateint experienced possible cardiomyopathy and dilated left ventricle whilst being treated with Clopine.	
Dilatation ventricular			

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
Tablet	600 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 24/05/2006 <b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 238132**

**Data Entry Date :** 20/02/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 43

**Onset Date :** 17/12/2007

**Age :**

**DOB :** 28/02/1952

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** Patient has a 6 year history of schizophrenia.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Eosinophilia		Eosinophilia. Patient began experiencing a fever which was described as severe in intensity. Patient was also suffering from urinary incontinence and a headache and had raised inflammatory markers (white blood cell count, neutrophils and C-reactive protien).	Clopine ceased.
Headache			
Pyrexia			
Urinary incontinence			

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	75 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 05/12/2007	<b>Stopped :</b> 04/01/2008	

# Public Case Detail

Cases Count: 393

**Case Number : 238272**

**Data Entry Date :** 25/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 20/12/2007

**Age :**

**DOB :** 11/06/1949

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Blood creatine phosphokinase increased		Afer 5 years starting Clozaril, the patient had a significant rise in creatine kinase levels.	Clozaril was discontinued.
Myopathy			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	500 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 21/01/2003	<b>Stopped :</b> 20/12/2007	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Troponin				The patient's troponin were normal.
Creatine phosphokinase		20/12/2007	3743	

# Public Case Detail

Cases Count: 393

**Case Number : 238290**

**Data Entry Date :** 26/02/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 30/01/2008

**Age :**

**DOB :** 29/09/1981

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Salivary gland enlargement		Patient experienced salivary gland swelling.	Antibiotics and Ibruprofen.

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	625 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 07/03/2006	<b>Stopped :</b>	
<b>RISPERDAL (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 238291**

**Data Entry Date :** 26/02/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 21/01/2008

**Age :**

**DOB :** 10/10/1980

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Diarrhoea		Patient experienced eosinophil count increased, white blood count increased, neutrophil count increased, and symptoms of diarrhoea.	
Eosinophilia			
Neutrophil count increased			
White blood cell count increased			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	250 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 07/01/2008	<b>Stopped :</b>	



# Public Case Detail

Cases Count: 393

**Case Number : 238347**

**Data Entry Date :** 27/02/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/08/2003

**Age :**

**DOB :** 01/05/1984

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Palpitations		The patient developed sinus tachycardia in Aug 2003 approximately 8 weeks after commencing Clozaril.	Clozaril discontinued
Electrocardiogram QT prolonged			
Sinus tachycardia			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 19/06/2003	<b>Stopped :</b> 30/12/2007	
<b>BENZTROPINE MESYLATE (Other drug)</b>		<b>Reason :</b>	
Tablet	2 Milligram		Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>MIRTAZAPINE (Other drug)</b>		<b>Reason :</b>	
Tablet			
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>SODIUM VALPROATE (Other drug)</b>		<b>Reason :</b>	
Tablet			
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Heart Rate				120 - 140 beats per minute for the last week

# Public Case Detail

Cases Count: 393

**Case Number : 238358**

**Data Entry Date :** 27/02/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 05/02/2008

**Age :**

**DOB :** 27/03/1970

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Diabetic ketoacidosis		Patient developed diabetic ketoacidosis. Agranulocytosis.	Remain off Clozaril
Neutrophil count decreased			
White blood cell count decreased			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	250 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 03/12/2007	<b>Stopped :</b> 05/02/2008	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells	(4.5-11.0)	03/12/2007	5.80	
White blood cells	(4.5-11.0)	05/02/2008	2.40	
Neutrophils	(18-7.7)	03/12/2007	4.00	
Neutrophils	(18-7.7)	05/02/2008	1.20	

# Public Case Detail

Cases Count: 393

**Case Number : 238426**

**Data Entry Date :** 29/02/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 06/02/1957

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** The patient parasitic infection is alternative explanation of eosinophilia.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Eosinophilia		Patient developed the eosinophilia in the 4th week of treatment. The patient is also suffering from a parasitic infection ('parasite condition') and is presenting with diarrhoea and elevated white blood cells.	
Infection parasitic			
Leukocytosis			

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
Tablet	300 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 01/01/2008 <b>Stopped :</b> 10/02/2008 <b>Contin</b>
<b>METFORMIN HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>OLANZAPINE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>SODIUM VALPROATE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Eosinophils				Eosinophils 10.78.

## Case Number : 238427

Data Entry Date : 29/02/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 05/02/2008

Age :

DOB : 17/11/1964

Outcome :

Causality : Causality probable

Not yet recovered

### Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Leukopenia	Caused or prolonged inpatient hospitalisation	During routine blood examinations it was revealed that the patient had severe neutropenia and leucopenia (assessed as life threatening and severe). This was described as marked neutropenia secondary to clozapine treatment.	Clopine was ceased.
Agranulocytosis	Caused or prolonged inpatient hospitalisation		

### Medicine details :

<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia		
Tablet	500 Milligram	Daily	Oral	
<b>Batch :</b>	<b>Started :</b> 17/12/2007	<b>Stopped :</b> 05/02/2008		
<b>DIAZEPAM (Other drug)</b>		<b>Reason :</b> Anxiety neurosis		
Tablet	5 Milligram	As necessary	Oral	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>		
<b>LITHIUM CARBONATE (Other drug)</b>		<b>Reason :</b>		
Tablet	900 Milligram		Oral	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>		
<b>MIRTAZAPINE (Other drug)</b>		<b>Reason :</b> Depression		
Tablet	30 Milligram	Daily	Oral	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>		

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		29/01/2008	7.40	
White blood cells		05/02/2008	2.00	
White blood cells		06/02/2008	1.60	
Neutrophils		29/01/2008	5.30	
Neutrophils		05/02/2008	0.01	
Neutrophils		06/02/2008	0.03	

# Public Case Detail

Cases Count: 393

**Case Number : 238456**

**Data Entry Date :** 29/02/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 20/07/1948

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Agranulocytosis	Caused or prolonged inpatient hospitalisation	Patient experienced agranulocytosis-progressive neutropenia and fever.	IV antibiotics and GCSF.
Pyrexia	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>	
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
<b>Batch :</b>	<b>Started :</b> 29/10/2007 <b>Stopped :</b>

## Case Number : 238551

**Data Entry Date :** 04/03/2008

**Gender :** F

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 06/12/1960

**Outcome :**

**Causality :** Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Weight increased	Caused or prolonged inpatient hospitalisation	Patient experienced weight gain and hepatitis.	Clopine ceased.
Hepatic function abnormal	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

**CLOPINE (Suspected)**

**Reason :**

Tablet

50 Milligram

Daily

Oral

**Batch :**

**Started :** 04/01/2008

**Stopped :** 04/01/2008

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				White blood cell count and neutrophil counts normal.

# Public Case Detail

Cases Count: 393

**Case Number : 238583**

**Data Entry Date :** 04/03/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 05/02/2008

**Age :**

**Outcome :** 09/02/2008

**DOB :** 04/02/1961

Recovered

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Patient developed myocarditis which manifested as generalised flu-like illness and fatigue.	Ceased Clopine
Troponin I increased			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	250 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 25/01/2008	<b>Stopped :</b> 08/02/2008	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Troponin		06/02/2008	0.10	baseline <0.05
Troponin		08/02/2008	0.09	baseline <0.05

# Public Case Detail

Cases Count: 393

**Case Number : 238805**

**Data Entry Date :** 11/03/2008

**Hospitalisation :**

**Onset Date :** 15/10/2007

**Outcome :**  
Unknown

**Gender :** M

**Weight (kg) :** 0

**Age :**

**DOB :** 14/02/1957

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Cardiomyopathy		Cardiomyopathy.	Clopine ceased.

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	275 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 27/08/2007	<b>Stopped :</b> 30/10/2007	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Echocardiogram				10/2007: Abnormal cardiomyopathy.



# Public Case Detail

Cases Count: 393

**Case Number : 238872**

**Data Entry Date :** 12/03/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 06/02/2008

**Age :**

**DOB :** 30/07/1969

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Patient developed myocarditis.	Clozaril discontinued.

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 22/01/2008	<b>Stopped :</b>	06/02/2008

# Public Case Detail

Cases Count: 393

**Case Number : 238873**

**Data Entry Date :** 12/03/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 13/02/2008

**Age :**

**DOB :** 27/08/1963

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Patient developed myocarditis.	

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	125 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 31/01/2008	<b>Stopped :</b>	14/02/2008

# Public Case Detail

Cases Count: 393

**Case Number : 238905**

**Data Entry Date :** 13/03/2008

**Gender :** M

**Hospitalisation :** Required a specialist consultation

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 02/06/1975

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Myocarditis		The suspected myocarditis presented as chest pain, tachycardia, fever of (38c), elevated troponin, elevated creatine kinase (CK) and elevated C- reactive protein (CRP). The patient was symptomatic and was unwell.	Clopine ceased.
Blood creatine phosphokinase increased			
C-reactive protein increased			
Chest pain			
Pyrexia			
Tachycardia			
Troponin increased			

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
Tablet	100 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 11/02/2008 <b>Stopped :</b> 19/02/2008

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Electrocardiography				An electrocardiogram was completed revealing subtle changes. Not specified.

# Public Case Detail

Cases Count: 393

**Case Number : 238907**

**Data Entry Date :** 13/03/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 15/01/2008  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 19/11/1973  
**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Dystonia	Caused or prolonged inpatient hospitalisation	Acute muscle dystonia; spasm lasted for a few minutes then ceased then restarted, all day, becoming worse. The spasms affected his face, mouth and limbs and was distressing for him.	Treated with Cogentin.
Muscle spasms	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	75 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

## Case Number : 238936

Data Entry Date : 13/03/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 27/12/2007

Age :

DOB : 25/09/1958

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Diabetes mellitus		Treatment was discontinued on 27 Dec 2007 due to the onset of diabetes, lack of efficacy, patient's objection to regular blood tests and weight gain. On unspecified dates the patient experienced panic attacks, paranoid ideation with ego dystonic (almost delusion) ideation in spite of treatment with Clozapine and Aropax (paroxetine hydrochloride) and Valproate.	Clozaril treatment was discontinued.
Delusion			
Drug ineffective			
Panic attack			
Paranoia			
Weight increased			

#### Medicine details :

<b>AROPAX (Suspected)</b>	Reason :
Batch :	Started : Stopped :
<b>CLOZARIL (Suspected)</b>	Reason :
Tablet	Oral
Batch :	Started : 27/06/1994 Stopped : 27/12/2007
<b>VALPRO (Suspected)</b>	Reason :
Batch :	Started : Stopped :

# Public Case Detail

Cases Count: 393

**Case Number : 239132**

**Data Entry Date :** 19/03/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 09/08/1964

**Outcome :**

**Causality :** Causality probable

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Agranulocytosis		43 year old patient who ceased treatment with Clopine due to neutropenia, leucopenia and agranulocytosis.	Clopine was ceased on 26 Feb 2008 as a result of the events.
Leukopenia			
Neutropenia			

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
Tablet	350 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 15/10/2005 <b>Stopped :</b> 26/02/2008

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
White blood cells		29/02/2008	3.30	(x 10 <sup>9</sup> L)
White blood cells		28/02/2008	3.10	(x 10 <sup>9</sup> L)
White blood cells		27/02/2008	4.30	(x 10 <sup>9</sup> L)
White blood cells		26/02/2008	2.20	(x 10 <sup>9</sup> L)
White blood cells		22/02/2008	3.70	(x 10 <sup>9</sup> L)
White blood cells		20/02/2008	3.30	(x 10 <sup>9</sup> L)
White blood cells		15/02/2008	3.90	(x 10 <sup>9</sup> L)
Neutrophils		29/02/2008	1.10	(x 10 <sup>9</sup> L)
Neutrophils		28/02/2008	1.30	(x 10 <sup>9</sup> L)
Neutrophils		27/02/2008	2.90	(x 10 <sup>9</sup> L)
Neutrophils		26/02/2008	0.80	(x 10 <sup>9</sup> L)
Neutrophils		22/02/2008	1.90	(x 10 <sup>9</sup> L)
Neutrophils		20/02/2008	1.50	(x 10 <sup>9</sup> L)
Neutrophils		15/02/2008	2.20	(x 10 <sup>9</sup> L)
Serum drug level		29/02/2008	0.0	Clopine
Serum drug level		28/02/2008	0.0	Clopine
Serum drug level		27/02/2008	0.0	Clopine
Serum drug level		26/02/2008	0.0	Clopine

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Serum drug level		22/02/2008	350.0	Clopine
Serum drug level		20/02/2008	350.0	Clopine
Serum drug level		15/02/2008	350.0	Clopine

# Public Case Detail

Cases Count: 393

## Case Number : 239147

**Data Entry Date :** 20/03/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 19/02/2008  
**Outcome :** 22/02/2008  
 Recovered

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 11/08/1978  
**Causality :** Causality certain

**Information:** Cert (L.D.)

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Drug toxicity	Caused or prolonged inpatient hospitalisation	A 29 year old male who ceased treatment with Clopine due to tachycardia.	Clopine was ceased and the patient was admitted to hospital and monitored for 4 days.
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	450 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 01/02/2008	<b>Stopped :</b> 19/02/2008	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
White blood cells				The patient's white blood cell and neutrophil counts were within normal limits for the treatment period.
Neutrophils				The patient's white blood cell and neutrophil counts were within normal limits for the treatment period.
Other data				Blood clozapine levels (date unknown) - Increased



# Public Case Detail

Cases Count: 393

**Case Number : 239233**

**Data Entry Date :** 26/03/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 22/02/2008

**Age :**

**DOB :** 19/10/1961

**Outcome :** 22/02/2008

**Causality :** Causality possible

Death

**Information:** FI provides additional patient history but cause of death still not yet available

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Death	Death	46 year old male patient died due to unknown reasons whilst being treated with Clopine.	

## Medicine details :

<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 23/01/2007	L TERM	<b>Stopped :</b>

## Case Number : 239266

Data Entry Date : 26/03/2008

Gender : M

Hospitalisation :

Weight (kg) : 60

Onset Date : 03/03/2008

Age :

DOB : 12/09/1945

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Myocarditis	Normal saline, anginine SL
Chest pain	Caused or prolonged inpatient hospitalisation		
Hypokinesia	Caused or prolonged inpatient hospitalisation		
Hypotension	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	175 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 19/02/2008 <b>Stopped :</b> 04/03/2008
<b>EPILIM (Other drug)</b>	<b>Reason :</b>
	1.2 Gram Daily
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>SOLIAN (Other drug)</b>	<b>Reason :</b>
	300 Milligram Daily
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>TEMAZEPAM (Other drug)</b>	<b>Reason :</b>
	20 Milligram As necessary
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>TRIMETHOPRIM (Other drug)</b>	<b>Reason :</b>
	300 Milligram Daily
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				Myocarditis confirmed with echocardiogram. Echo on 07/03 showed normal cavity size and wall thickness of LV but mildly impaired contraction with diffuse hypokinesia. EF is 48% troponin was 0.04 microg/l on 05/03 and 0.01 on 06/03, oesinophil 0.3 on 05/03, 0.2 on 06/03, 0.5 on 10/03.

# Public Case Detail

Cases Count: 393

**Case Number : 239308**

**Data Entry Date :** 27/03/2008

**Gender :** F

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Onset Date :** 18/04/2007

**Age :** 33Y

**Outcome :**

**DOB :**

Recovered

**Causality :** Causality probable

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Neutropenia	Caused or prolonged inpatient hospitalisation	Neutropenia	Clozapine ceased.

<b>Medicine details :</b>	
<b>CLOZAPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
<b>Batch :</b>	<b>Started :</b> 26/03/2007 <b>Stopped :</b> 18/04/2007

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		19/04/2007	5.1	
Neutrophils		19/04/2007	1.9	
Neutrophils		21/04/2007	6.1	

# Public Case Detail

Cases Count: 393

**Case Number : 239365**

**Data Entry Date :** 31/03/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 24/11/1951

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Convulsion		Patient experienced seizure and/or increase seizures.	Clozaril was discontinued.

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	112.5 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 02/03/1998	<b>Stopped :</b> 03/03/2008	

**Case Number : 239377**

**Data Entry Date :** 31/03/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 72

**Onset Date :** 06/02/2008

**Age :**

**DOB :** 08/01/1937

**Outcome :** 25/02/2008

**Causality :** Causality possible

Recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Hepatitis	Life threatening	Decreased liver function	Clozapine ceased

**Medicine details :**

<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 19/06/2007	<b>Stopped :</b> 08/02/2008	
<b>LITHIUM CARBONATE (Other drug)</b>		<b>Reason :</b> Prophylaxis	
Tablet	1 Gram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
SAP = ALP		06/02/2008	684	
GGT = SGGT = GGTP		06/02/2008	346	
ALT = SGPT		06/02/2008	344	
AST = SGOT		06/02/2008	245	
Bilirubin		06/02/2008	Normal	

# Public Case Detail

Cases Count: 393

**Case Number : 239379**

**Data Entry Date :** 31/03/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 23/02/2008

**Age :**

**DOB :** 14/10/1944

**Outcome :** 23/02/2008

**Causality :** Causality possible

Death

**Information:** FI indicates death possibly due to cardiac arrhythmia but coroner's report not yet available

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Death	Death	Unexplained death	

## Medicine details :

<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 29/11/2006	<b>Stopped :</b> 23/02/2008	

# Public Case Detail

Cases Count: 393

**Case Number : 239389**

**Data Entry Date :** 31/03/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 18/05/1962

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Paraesthesia		Rapid heart beat, drooling and tingling of the arms and legs.	
Drooling			
Heart rate increased			
Salivary hypersecretion			

**Medicine details :**

CLOZARIL (Suspected)	Reason :	Oral
Batch :	Started :	Stopped :



# Public Case Detail

Cases Count: 393

**Case Number : 239438**

**Data Entry Date :** 01/04/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 12/03/2008  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 28/12/1986  
**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Convulsion	Caused or prolonged inpatient hospitalisation	Seizure.	

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 19/12/2007	<b>Stopped :</b>	Ongoing.
<b>EPILIM (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 239439**

**Data Entry Date :** 01/04/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 02/03/2008

**Age :**

**DOB :** 09/07/1986

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Convulsion		Seizure.	

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	125 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b> 21/02/2002	

# Public Case Detail

Cases Count: 393

**Case Number : 239457**

**Data Entry Date :** 01/04/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 17/12/2007

**Age :**

**Outcome :** 15/03/2008

**DOB :** 28/04/1942

Recovered

**Causality :** Causality probable

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Leukopenia		Patient experienced severe leucopenia and neutropenia.	Clopine ceased.
Neutropenia			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	225 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 24/02/2004	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		17/12/2007	2.80	WCC (x10 <sup>9</sup> /L)
White blood cells		22/11/2007	5.20	WCC (x10 <sup>9</sup> /L)
White blood cells		16/03/2008	3.90	WCC (x10 <sup>9</sup> /L)
White blood cells		15/03/2008	3.40	WCC (x10 <sup>9</sup> /L)
White blood cells		14/03/2008	2.60	WCC (x10 <sup>9</sup> /L)
White blood cells		13/03/2008	1.30	WCC (x10 <sup>9</sup> /L)
White blood cells		12/03/2008	1.90	WCC (x10 <sup>9</sup> /L)
White blood cells		10/03/2008	2.20	WCC (x10 <sup>9</sup> /L)
White blood cells		11/02/2008	5.30	WCC (x10 <sup>9</sup> /L)
White blood cells		15/01/2008	3.70	WCC (x10 <sup>9</sup> /L)
White blood cells		08/01/2008	3.80	WCC (x10 <sup>9</sup> /L)
White blood cells		02/01/2008	3.30	WCC (x10 <sup>9</sup> /L)
White blood cells		17/12/2007	2.80	WCC (x10 <sup>9</sup> /L)
White blood cells		22/11/2007	5.20	WCC (x10 <sup>9</sup> /L)
Neutrophils		17/12/2007	2.10	NC (x10 <sup>9</sup> /L)
Neutrophils		22/11/2007	4.30	NC (x10 <sup>9</sup> /L)
Neutrophils		16/03/2008	2.20	NC (x10 <sup>9</sup> /L)
Neutrophils		15/03/2008	2.20	NC (x10 <sup>9</sup> /L)
Neutrophils		14/03/2008	1.40	NC (x10 <sup>9</sup> /L)
Neutrophils		13/03/2008	0.60	NC (x10 <sup>9</sup> /L)
Neutrophils		12/03/2008	1.20	NC (x10 <sup>9</sup> /L)

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		10/03/2008	1.50	NC (x10 <sup>9</sup> /L)
Neutrophils		11/02/2008	4.30	NC (x10 <sup>9</sup> /L)
Neutrophils		15/01/2008	2.80	NC (x10 <sup>9</sup> /L)
Neutrophils		08/01/2008	2.90	NC (x10 <sup>9</sup> /L)
Neutrophils		02/01/2008	2.20	NC (x10 <sup>9</sup> /L)
Neutrophils		17/12/2007	2.10	NC (x10 <sup>9</sup> /L)
Neutrophils		22/11/2007	4.30	NC (x10 <sup>9</sup> /L)
Other data		17/12/2007	225.0	Dose (MG)
Other data		22/11/2007	225.0	Dose (MG)
Other data		16/03/2008	0.0	Dose (MG)
Other data		15/03/2008	0.0	Dose (MG)
Other data		14/03/2008	0.0	Dose (MG)
Other data		13/03/2008	0.0	Dose (MG)
Other data		12/03/2008	225.0	Dose (MG)
Other data		10/03/2008	225.0	Dose (MG)
Other data		11/02/2008	225.0	Dose (MG)
Other data		15/01/2008	225.0	Dose (MG)
Other data		08/01/2008	225.0	Dose (MG)
Other data		02/01/2008	225.0	Dose (MG)
Other data		17/12/2007	225.0	Dose (MG)
Other data		22/11/2007	225.0	Dose (MG)

# Public Case Detail

Cases Count: 393

**Case Number : 239475**

**Data Entry Date :** 02/04/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 12/03/2008  
**Outcome :** 07/04/2008  
 Death, maybe drug

**Gender :** F  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 24/04/1980  
**Causality :** Causality probable

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Leukopenia	Death	Patient experienced neutropenia and leucopenia whilst on treatment with Clopine.	Clopine ceased. ICU.
Agranulocytosis	Life threatening		
Infection	Life threatening		
Neutropenia	Life threatening		

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	350 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 26/01/2008	<b>Stopped :</b> 12/03/2008	0

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		05/03/2008	8.10	Unknown date: 1.00. Dose 350.0
Neutrophils		05/03/2008	6.10	Date unknown: 0.00. Dose 350.0
Serum drug level		05/03/2008	350.0	Clopine Unknown date = 350.0mg 05/03/08 = 350.0mg

# Public Case Detail

Cases Count: 393

**Case Number : 239494**

**Data Entry Date :** 02/04/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 28/12/1944

**Outcome :**

**Causality :** Causality possible

Death

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Pulmonary embolism	Death	Patient died from a pulmonary embolism secondary to a deep vein thrombosis whilst being treated with Clopine.	
Deep vein thrombosis	Death		

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
	300 Milligram Daily
<b>Batch :</b>	<b>Started :</b> 04/10/2006 L TERM <b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 239564**

**Data Entry Date :** 03/04/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/02/2008

**Age :**

**DOB :** 03/06/1976

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Patient ceased treatment with Clopine due to myocarditis.	Ceased Clopine

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 12/02/2008	<b>Stopped :</b>	28/02/2008

# Public Case Detail

Cases Count: 393

**Case Number : 239586**

**Data Entry Date :** 04/04/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 25/07/1980

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis	Ceased clozapine

**Medicine details :**

<b>CLOZAPINE (Suspected)</b>	<b>Reason :</b>
Tablet	175 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 27/02/2008 <b>Stopped :</b> 13/03/2008



## Case Number : 239693

**Data Entry Date :** 08/04/2008

**Gender :** M

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 87

**Onset Date :** 06/02/2008

**Age :**

**DOB :** 04/10/1983

**Outcome :**

**Causality :** Causality possible

Unknown

### Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy	Caused or prolonged inpatient hospitalisation	Patient experienced a relapse of his psychosis characterised by paranoia and severe thought disorder in the context of Clozaril non-compliance and was admitted to hospital. Clozaril was recommenced and increased to 450mg. On the higher dose the patient began to show some improvement in his mental state. On approximately 16 Feb 08 the patient developed a sinus tachycardia with a heart rate of about 120. A cardiac MRI performed on 18 Feb 08 showed moderate idiopathic cardiomyopathy but no evidence of active myocarditis.	Cardiology unit advised discontinuation of Clozaril.
Paranoia	Caused or prolonged inpatient hospitalisation		
Psychotic disorder	Caused or prolonged inpatient hospitalisation		
Sinus tachycardia	Caused or prolonged inpatient hospitalisation		
Thinking abnormal	Caused or prolonged inpatient hospitalisation		
Treatment noncompliance	Caused or prolonged inpatient hospitalisation		

### Medicine details :

**CLOZARIL (Suspected)**

**Reason :** Unspecified psychosis

450 Milligram Daily

**Batch :**

**Started :** 14/08/2007

**Stopped :**

0

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		12/08/2007	9.51 x 10 <sup>9</sup> /L	
Neutrophils		12/08/2007	5.54 x 10 <sup>9</sup> /L	
Echocardiogram				26 Feb 08. Mild to moderately dilated Left Ventricle (LV) with mild to moderate systolic dysfunction. Mild Left Atrium (LA) dilation.
Magnetic Resonance Imaging				18 Feb 08. Cardiac MRI report showed moderate idiopathic cardiomyopathy but no evidence of active myocarditis.

# Public Case Detail

Cases Count: 393

**Case Number : 239738**

**Data Entry Date :** 08/04/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 23/08/1983

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Weight increased		Patient's weight increased significantly, about 50kg to 90kg in about 3-4 months and she had developed significant abdominal obesity.	
Central obesity			

**Medicine details :**

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	125 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 19/05/2003	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 239904**

**Data Entry Date :** 14/04/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 29/02/2008

**Age :**

**DOB :** 05/12/1980

**Outcome :**

**Causality :** Causality probable

Recovered

## Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient ceased treatment with Clopine due to myocarditis. Temperature spike. Troponin increased.	Ceased Clopine
Electrocardiogram ST segment elevation			
Pyrexia			
Troponin increased			

### Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	225 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 18/02/2008	<b>Stopped :</b> 29/02/2008	

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin		29/02/2008	0.14	
Heart Rate				? March 2008 Tachycardia
White blood cells		07/03/2008	13.60	
White blood cells		03/03/2008	12.10	
Neutrophils		07/03/2008	9.17	
Neutrophils		03/03/2008	7.22	
Serum drug level		07/03/2008	175.0	Clopine
Serum drug level		03/03/2008	175.0	Clopine
Electrocardiography				On 13 Mar 2008 patient developed ECG changes (ST elevation). A cardiologists investigation diagnosed the patient as having myocarditis and clozapine was ceased.

## Case Number : 239907

**Data Entry Date :** 14/04/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 13/05/2007  
**Outcome :**  
 Recovered

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 13/04/1969  
**Causality :** Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Lethargy	Caused or prolonged inpatient hospitalisation	Patient was transferred to hospital on the 13/5/07 due to a three day history of lethargy. The patient spiked a temperature of 39.4 degrees. He also had a productive cough and was tachycardic on admission. He was diagnosed as having pneumonia but his chest x-ray was clear.	Treated for pneumonia, IV penicillin for 3 days then amoxicillin.
Cough	Caused or prolonged inpatient hospitalisation		
Lower respiratory tract infection	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

<b>CLOZAPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
150 Milligram Daily	
<b>Batch :</b>	<b>Started :</b> 30/04/2007 <b>Stopped :</b>
<b>LORAZEPAM (Other drug)</b>	<b>Reason :</b>
1 Milligram	
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>RISPERIDONE (Other drug)</b>	<b>Reason :</b>
Injection 37.5 Milligram	Intramuscular
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 239965**

**Data Entry Date :** 15/04/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 12/05/1982

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Urinary incontinence		Patient complained of urinary incontinence had become worse and gained 50 kg.	
Weight increased			

**Medicine details :**

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>
Tablet	600 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 20/02/2006 <b>Stopped :</b>

## Case Number : 239992

Data Entry Date : 15/04/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 19/03/2008

Age :

DOB : 08/09/1988

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Loss of consciousness		On 19 March 08 patient experienced a loss of consciousness and postural hypotension both described as moderate in severity. Electrocardiogram changes and dyslipidemia.	Clopine ceased.
Dyslipidaemia			
Electrocardiogram change			
Orthostatic hypotension			

#### Medicine details :

<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	25 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 18/03/2008	<b>Stopped :</b> 24/03/2008	
<b>LITHIUM CARBONATE (Other drug)</b>		<b>Reason :</b> Unspecified schizophrenia	
	1000 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography		24/03/2008	Abnormal	
Triglyceride		24/03/2008	20.6	(Ref range <2.0)
Cholesterol		24/03/2008	7.8	(Ref range <5.5)

# Public Case Detail

Cases Count: 393

**Case Number : 240021**

**Data Entry Date :** 15/04/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 27/03/2008

**Age :**

**DOB :** 17/07/1958

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced severe neutropenia and leucopenia.	Clopine ceased.
Leukopenia			

**Medicine details :**

CLOPINE (Suspected)	Reason :
Tablet	700 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
White blood cells		01/04/2008	3.10	WBC
White blood cells		31/03/2008	2.79	WBC
White blood cells		28/03/0200	3.40	WBC
White blood cells		27/03/2008	3.90	WBC
White blood cells		25/03/0200	3.70	WBC
White blood cells		25/02/0200	6.40	WBC
White blood cells		29/01/0200	6.60	WBC
Neutrophils		01/04/2008	1.49	NC
Neutrophils		31/03/2008	0.92	NC
Neutrophils		28/03/0200	1.86	NC
Neutrophils		27/03/2008	1.43	NC
Neutrophils		25/03/0200	1.41	NC
Neutrophils		25/02/0200	3.69	NC
Neutrophils		29/01/0200	3.63	NC
Other data		01/04/2008	700.0	Dose (MG/DAY).
Other data		31/03/2008	700.0	Dose (MG/DAY).
Other data		28/03/0200	700.0	Dose (MG/DAY).
Other data		27/03/2008	700.0	Dose (MG/DAY).



**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Other data		25/03/0200	700.0	Dose (MG/DAY).
Other data		25/02/0200	700.0	Dose (MG/DAY).
Other data		29/01/0200	700.0	Dose (MG/DAY).

# Public Case Detail

Cases Count: 393

**Case Number : 240045**

**Data Entry Date :** 16/04/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 20/03/2008

**Age :**

**DOB :** 13/10/1989

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Pericardial effusion		Patient experienced pericardial efusion and left ventricular hypertrophy. Resting pulse was 90 to 110 beats per minutes.	Clopine was being reduced from 350mg by 50mg every 2 days to Zero.
Heart rate increased			
Left ventricular hypertrophy			

**Medicine details :**

<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	350 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 31/01/2008	<b>Stopped :</b>	
<b>VENLAFAXINE HYDROCHLORIDE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b> 15/09/0207	<b>Stopped :</b>	

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Echocardiogram				Echocardiogram which confirmed the mild pericardial effusion on 20/Mar/2008. Also identified borderline left ventricular hypertrophy.

# Public Case Detail

Cases Count: 393

**Case Number : 240065**

**Data Entry Date :** 16/04/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 28/08/1962

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Patient developed cardiomyopathy after his echocardiogram in Jan 2008, patient was initially on 700 mg and dose reduced to 350 mg then patient became psychotic.	
Mental impairment			
Psychotic disorder			
Treatment noncompliance			
Ventricular dysfunction			

**Medicine details :**

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 03/03/2008	<b>Stopped :</b>	
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	350 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	700 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 01/10/2007	<b>Stopped :</b> 02/03/2008	

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Echocardiogram				Echocardiogram showed a decreased in left ventricular function.

# Public Case Detail

Cases Count: 393

**Case Number : 240067**

**Data Entry Date :** 16/04/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 07/07/1983

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:** Clopine treatment was ceased on 29-Mar-2008. The patient was admitted to hospital and is currently in the intensive care unit (ICU).

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome	Clopine was ceased and currently is in ICU.

## Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	650 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 26/02/2007	<b>Stopped :</b> 29/03/2008	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells				Normal
Neutrophils				Normal

## Case Number : 240155

Data Entry Date : 18/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 134

Onset Date :

Age :

DOB : 19/06/1979

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Metabolic syndrome	Caused or prolonged inpatient hospitalisation	Patient experienced metabolic syndrome, elevated alt,and GGT.	Clopine was swapped to amisulpride.
Hepatic function abnormal	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	350 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 24/09/2004 <b>Stopped :</b>
<b>AMITRIPTYLINE HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>ATORVASTATIN (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>METFORMIN HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>PANTOPRAZOLE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>QUETIAPINE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Liver function tests				Elevated ALT and GGT to 5 times the normal level.

# Public Case Detail

Cases Count: 393

**Case Number : 240188**

Data Entry Date : 21/04/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 18/01/2008

Age : 35Y

Outcome :

DOB :

Not yet recovered

Causality : Causality possible

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Ejaculation failure		Unable to ejaculate.	Aripiprazole and propranolol ceased.

<b>Medicine details :</b>			
<b>Aripiprazole (Suspected)</b>		<b>Reason :</b>	
Tablet	30 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b> 19/01/2008	
<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b>	
	500 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>PROPRANOLOL HYDROCHLORIDE (Suspected)</b>		<b>Reason :</b>	
	20 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b> 18/01/2008	
<b>VALPRO (Suspected)</b>		<b>Reason :</b>	
Tablet	2.5 Gram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

## Case Number : 240496

**Data Entry Date :** 30/04/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 12/03/2008  
**Outcome :** 07/04/2008  
 Death

**Gender :** F  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 24/04/1980  
**Causality :** Causality probable

**Information:** Neutropenia and agranulocytosis

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Chest pain	Life threatening	Chest pain, dizziness, vomiting, fever, sore throat, headache and abdominal pain.	
Abdominal pain	Life threatening		
Dizziness	Life threatening		
Headache	Life threatening		
Neutropenia	Life threatening		
Oropharyngeal pain	Life threatening		
Pyrexia	Life threatening		
Sepsis	Life threatening		
Vomiting	Life threatening		

### Medicine details :

<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	350 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 26/01/2008	<b>Stopped :</b>	12/03/2008

# Public Case Detail

Cases Count: 393

**Case Number : 240528**

**Data Entry Date :** 01/05/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 21/01/2008

**Age :**

**DOB :** 01/07/1962

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** Possible hypersplenism.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia and thrombocytopenia.	
Thrombocytopenia			

## Medicine details :

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet			Oral
<b>Batch :</b>	<b>Started :</b> 22/04/2003	L TERM	<b>Stopped :</b>
<b>CITALOPRAM HYDROBROMIDE (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>		<b>Stopped :</b>
<b>COLOXYL (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>		<b>Stopped :</b>
<b>HYOSCINE NOS (Other drug)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b>		<b>Stopped :</b>

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Hepatitis C antibody				Chronic hepatitis C (liver function test abnormal).
Platelets				Platelet count abnormal.
White blood cells		03/12/2007	3.88	Date unknown WBC: 425
White blood cells		27/12/2007	3.21	Date unknown WBC: 425
White blood cells		21/01/2008	2.66	Date unknown WBC: 425
White blood cells		22/01/2008	3.13	Date unknown WBC: 425
Neutrophils		03/12/2007	1.90	Pre - 2003 Date unknown NC: 2.3 and 1.6
Neutrophils		27/12/2007	2.00	Pre - 2003 Date unknown NC: 2.3 and 1.6
Neutrophils		22/01/2008	1.8	Pre - 2003 Date unknown NC: 2.3 and 1.6





## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		16/08/2007	5.90	
Neutrophils		19/07/2007	4.40	
Other data		04/04/2008	0.0	Dose of Clopine
Other data		29/02/2008	125.0	Dose of Clopine
Other data		05/02/2008	125.0	Dose of Clopine
Other data		07/01/2008	150.0	Dose of Clopine
Other data		30/12/2007	175.0	Dose of Clopine
Other data		05/11/2007	200.0	Dose of Clopine
Other data		08/10/2007	225.0	Dose of Clopine
Other data		06/09/2007	250.0	Dose of Clopine
Other data		16/08/2007	300.0	Dose of Clopine
Other data		19/07/2007	325.0	Dose of Clopine

# Public Case Detail

Cases Count: 393

**Case Number : 240573**

**Data Entry Date :** 05/05/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 04/04/2008

**Age :**

**DOB :** 22/12/1970

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myopericarditis		Patient experienced myopericarditis.	

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 19/03/2008	<b>Stopped :</b>	04/04/2008

# Public Case Detail

Cases Count: 393

**Case Number : 240650**

**Data Entry Date :** 06/05/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 73Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality probable

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Neuroleptic malignant syndrome		Neuroleptic malignant syndrome, nausea, vomiting, pyrexia.	Clozaril was ceased.
Nausea			
Pyrexia			
Vomiting			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	75 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 27/03/2008	<b>Stopped :</b>	10/04/2008

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
GGT = SGGT = GGTP				GGT Increased. GGT elevated to 223.
C-Reactive Protein				CRP increased. CRP elevated to 35.

# Public Case Detail

Cases Count: 393

**Case Number : 240686**

**Data Entry Date :** 07/05/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 28/03/2007  
**Outcome :**  
 Not yet recovered

**Gender :** F  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 22/03/1967  
**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Weight increased	Caused or prolonged inpatient hospitalisation	Patient presented with weight gain and oversedation. Also recent diagnosis of non-insulin dependent diabetes mellitus was reported by the physician.	Clozaril was discontinued.
Sedation	Caused or prolonged inpatient hospitalisation		
Type 2 diabetes mellitus	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 27/10/2005	<b>Stopped :</b> 02/04/2008	0
<b>ENDONE (Other drug)</b>		<b>Reason :</b>	
	5 Milligram		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>PROLADONE (Other drug)</b>		<b>Reason :</b>	
	30 Milligram		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

## Case Number : 240752

**Data Entry Date :** 08/05/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 27/03/2008  
**Outcome :** 27/03/2008  
 Recovered

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 15/02/1983  
**Causality :** Causality possible

### Information:

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Drug level increased	Caused or prolonged inpatient hospitalisation	Drug level increased.	Luvox discontinued. Clozapine withheld and re-introduced.

<b>Medicine details :</b>			
<b>CLOPINE (Interaction)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	700 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 30/01/2007	<b>Stopped :</b>	0
<b>LUVOX (Interaction)</b>		<b>Reason :</b>	
Tablet	50 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/03/2008	<b>Stopped :</b> 27/03/2008	Discontinued.

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Serum drug level				Clozapine serum level increased to 2220.

# Public Case Detail

Cases Count: 393

**Case Number : 240832**

**Data Entry Date :** 13/05/2008

**Gender :** U

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 18/04/2008

**Age :**

**DOB :** 22/12/1982

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Patient developed myocarditis, pyrexia, dizziness, chest pain, hyperhidrosis, hypotension, Troponin increased.	Clozaril ceased.
Cardiac enzymes increased			
Chest pain			
Dizziness			
Electrocardiogram abnormal			
Hyperhidrosis			
Hypotension			
Pyrexia			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	225 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 01/04/2008	<b>Stopped :</b> 10/04/2008	0

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Troponin	>0.04	18/04/2008	0.29	Unknown dates troponin was 0.16 and 0.06.
Troponin	>0.04	22/04/2008	0.02	Unknown dates troponin was 0.16 and 0.06.
Erythrocyte sedimentation rate	2-12	19/04/2008	73	

# Public Case Detail

Cases Count: 393

**Case Number : 240841**

**Data Entry Date :** 13/05/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 17/04/2008

**Age :**

**DOB :** 01/03/1974

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient ceased Clopine treatment due to severe neutropenia and moderate leucopenia.	Ceased Clopine.
Leukopenia			

**Medicine details :**

CLOPINE (Suspected)	Reason :
Tablet	125 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 01/06/2004 <b>Stopped :</b> 17/04/2008

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
White blood cells		28/04/2008	2.50	(X10 <sup>9</sup> /L)
White blood cells		26/04/2008	3.50	(X10 <sup>9</sup> /L)
White blood cells		24/04/2008	3.10	(X10 <sup>9</sup> /L)
White blood cells		23/04/2008	2.60	(X10 <sup>9</sup> /L)
White blood cells		22/04/2008	2.70	(X10 <sup>9</sup> /L)
White blood cells		21/04/2008	3.00	(X10 <sup>9</sup> /L)
White blood cells		19/04/2008	3.00	(X10 <sup>9</sup> /L)
White blood cells		18/04/2008	3.00	(X10 <sup>9</sup> /L)
White blood cells		17/04/2008	2.80	(X10 <sup>9</sup> /L)
White blood cells		08/04/2008	4.70	(X10 <sup>9</sup> /L)
Neutrophils		28/04/2008	0.80	(X10 <sup>9</sup> /L)
Neutrophils		26/04/2008	1.30	(X10 <sup>9</sup> /L)
Neutrophils		24/04/2008	0.70	(X10 <sup>9</sup> /L)
Neutrophils		23/04/2008	0.70	(X10 <sup>9</sup> /L)
Neutrophils		22/04/2008	0.80	(X10 <sup>9</sup> /L)
Neutrophils		21/04/2008	1.00	(X10 <sup>9</sup> /L)
Neutrophils		19/04/2008	0.60	(X10 <sup>9</sup> /L)
Neutrophils		18/04/2008	0.80	(X10 <sup>9</sup> /L)
Neutrophils		17/04/2008	0.50	(X10 <sup>9</sup> /L)
Neutrophils		08/04/2008	2.10	(X10 <sup>9</sup> /L)



## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level		28/04/2008	0.0	(MG/DAY)
Serum drug level		26/04/2008	0.0	(MG/DAY)
Serum drug level		24/04/2008	0.0	(MG/DAY)
Serum drug level		23/04/2008	0.0	(MG/DAY)
Serum drug level		22/04/2008	0.0	(MG/DAY)
Serum drug level		21/04/2008	0.0	(MG/DAY)
Serum drug level		19/04/2008	0.0	(MG/DAY)
Serum drug level		18/04/2008	0.0	(MG/DAY)
Serum drug level		17/04/2008	125.0	(MG/DAY)
Serum drug level		08/04/2008	125.0	(MG/DAY)

## Case Number : 240844

Data Entry Date : 13/05/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 16/04/2008

Age :

DOB : 08/09/1987

Outcome : 23/04/2008

Causality : Causality possible

Recovered

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient ceased Clopine due to experiencing severe neutropenia.	Ceased Clopine.

#### Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	200 Milligram Daily
Batch :	Started : 12/12/2006
	Stopped : 16/04/2008

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		24/04/2008	7.98	
White blood cells		23/04/2008	6.91	
White blood cells		22/04/2008	5.66	
White blood cells		21/04/2008	4.47	
White blood cells		20/04/2008	4.49	
White blood cells		19/04/2008	4.46	
White blood cells		18/04/2008	4.09	
White blood cells		17/04/2008	4.95	
White blood cells		16/04/2008	4.30	
White blood cells		26/03/2008	6.50	
Neutrophils		24/04/2008	3.80	
Neutrophils		23/04/2008	2.30	
Neutrophils		22/04/2008	1.80	
Neutrophils		21/04/2008	1.10	
Neutrophils		20/04/2008	0.90	
Neutrophils		19/04/2008	0.90	
Neutrophils		18/04/2008	0.90	
Neutrophils		17/04/2008	1.60	
Neutrophils		16/04/2008	1.10	
Neutrophils		26/03/2008	3.10	
Serum drug level		24/04/2008	0.0	
Serum drug level		23/04/2008	0.0	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level		22/04/2008	0.0	
Serum drug level		21/04/2008	0.0	
Serum drug level		20/04/2008	0.0	
Serum drug level		19/04/2008	0.0	
Serum drug level		18/04/2008	0.0	
Serum drug level		17/04/2008	0.0	
Serum drug level		16/04/2008	0.0	
Serum drug level		26/03/2008	200.0	

## Case Number : 240855

Data Entry Date : 14/05/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome :

DOB : 06/03/1973

Recovered

Causality : Causality possible

**Information:** Current condition smoker, hypothyroidism, drug dependence cannabis abuse.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced neutropenia hallucinatory and delusional symptomatology, anxiety, mood swings increase in challenging behaviours.	Ceased Clozaril
Abnormal behaviour			
Anxiety			
Delusion			
Hallucination			
Mood swings			

### Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia
Tablet		Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b> 15/11/2006
<b>QUETIAPINE (Suspected)</b>		<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>
<b>SODIUM VALPROATE (Suspected)</b>		<b>Reason :</b> Anxiety neurosis
	4.5 Milligram Daily	Oral
<b>Batch :</b>	<b>Started :</b> 04/04/2008	<b>Stopped :</b>
<b>FISH OIL NOS (Other drug)</b>		<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>
<b>LITHIUM CARBONATE (Other drug)</b>		<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>
<b>LORAZEPAM (Other drug)</b>		<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> 15/04/2008	<b>Stopped :</b>
<b>MULTIVITAMINS (Other drug)</b>		<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> 15/04/2008	<b>Stopped :</b>

## Medicine details :

OLANZAPINE (Other drug)

Reason :

Batch :

Started : 08/04/2008

Stopped :

TRIFLUOPERAZINE HYDROCHLORIDE (Other drug)

Reason :

Batch :

Started :

Stopped :

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		09/11/2006	1.0	
Neutrophils		10/11/2006	1.0	

# Public Case Detail

Cases Count: 393

**Case Number : 240869**

**Data Entry Date :** 14/05/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 27/03/2008

**Age :**

**DOB :** 27/01/1962

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia	Clopine ceased

<b>Medicine details :</b>			
CLOPINE (Suspected)		Reason :	
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 17/02/2004	<b>Stopped :</b> 27/03/2008	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		14/04/2008	3.10	
White blood cells		11/04/2008	3.20	
White blood cells		10/04/2008	4.80	
White blood cells		07/04/2008	6.00	
White blood cells		03/04/2008	7.70	
White blood cells		02/04/2008	8.40	
White blood cells		01/04/2008	9.30	
White blood cells		27/03/2008	7.50 mg	Dose 300
White blood cells		10/03/2008	4.80 mg	Dose 300
Neutrophils		14/04/2008	0.90	
Neutrophils		11/04/2008	0.70	
Neutrophils		10/04/2008	0.60	
Neutrophils		07/04/2008	1.30	
Neutrophils		03/04/2008	1.80	
Neutrophils		02/04/2008	1.20	
Neutrophils		01/04/2008	1.00	
Neutrophils		27/03/2008	1.10	Dose 300 mg
Neutrophils		10/03/2008	2.60	Dose 300 mg

## Case Number : 240870

Data Entry Date : 14/05/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 29/10/1959

Outcome :

Causality : Causality possible

Unknown

Information: Diagnosed with hepatitis C in 1997. IV drug abuse.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Twelve days after starting therapy with Clozaril the patient developed neutropenia.	
White blood cell count decreased			

### Medicine details :

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	1 Dose Unspec Daily Oral
<b>Batch :</b>	<b>Started :</b> 09/02/2006 <b>Stopped :</b>
<b>CLONAZEPAM (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>HALOPERIDOL (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>METAMUCIL (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>MULTI-B FORTE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>RISPERIDONE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		29/03/1996	3.60 X 10 <sup>9</sup> /L	
Neutrophils		29/03/1996	1.40 X 10 <sup>9</sup> /L	

# Public Case Detail

Cases Count: 393

**Case Number : 240879**

**Data Entry Date :** 14/05/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 17/06/1983

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Convulsion		Seizures while on Clopine treatment.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	600 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 26/12/2007	<b>Stopped :</b>	



## Case Number : 240880

Data Entry Date : 14/05/2008

Gender : M

Hospitalisation : Hospitalisation prolonged

Weight (kg) : 0

Onset Date : 14/04/2008

Age :

DOB : 30/01/1986

Outcome :

Causality : Causality probable

Recovered

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation	Elevated CK, raised liver enzymes, increased ALT and AST and increased lactate dehydrogenase.	Ceased Clopine
Alanine aminotransferase increased	Caused or prolonged inpatient hospitalisation		
Aspartate aminotransferase increased	Caused or prolonged inpatient hospitalisation		
Blood lactate dehydrogenase increased	Caused or prolonged inpatient hospitalisation		
Hepatic enzyme increased	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	75 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 07/04/2008	<b>Stopped :</b> 14/04/2008	
<b>AMISULPRIDE (Other drug)</b>		<b>Reason :</b>	
	800 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/03/2008	<b>Stopped :</b>	

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase				On 14/04/08 the patient's CK levels increased from 250 to 22,000.
ALT = SGPT		14/04/2008	100	
AST = SGOT		14/04/2008	376	
LDH				957

# Public Case Detail

Cases Count: 393

**Case Number : 240896**

**Data Entry Date :** 14/05/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/12/2007

**Age :**

**DOB :** 13/02/1980

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** Estimated date of delivery was 14/3/08.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Drug exposure during pregnancy		Patient became pregnant whilst on Clopine. As of 11/9/07 all was well with the pregnancy and the patient had decided to continue with the pregnancy. However, at 22 weeks of the pregnancy the patient had a spontaneous foetal abortion (miscarriage).	
Abortion spontaneous			

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>	
Tablet	200 Milligram	Daily
		Oral
<b>Batch :</b>	<b>Started :</b> 12/03/1998	<b>Stopped :</b> 20/07/2007

# Public Case Detail

Cases Count: 393

## Case Number : 241014

Data Entry Date : 20/05/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 26/04/2008

Age :

Outcome : 26/04/2008

DOB : 15/02/1953

Unrelated death

Causality : Causality possible

### Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient died from septicaemia due to ruptured appendix whilst being treated with Clopine.	

Medicine details :			
CLOPINE (Suspected)	Reason :		
Tablet	750	Daily	Oral
Batch :	Started : 30/09/1997	Stopped :	26/04/2008

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
White blood cells				Patient's white cell and neutrophil counts were within normal limits for the treatment period with the exception of a few mildly rides results.
Neutrophils				Patient's white cell and neutrophil counts were within normal limits for the treatment period with the exception of a few mildly rides results.

# Public Case Detail

Cases Count: 393

**Case Number : 241078**

**Data Entry Date :** 20/05/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 25/03/1944

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Myocarditis.	Clopine ceased.

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	175 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 20/03/2008	<b>Stopped :</b> 03/04/2008	

## Case Number : 241085

Data Entry Date : 20/05/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/12/2007

Age :

DOB : 02/12/1952

Outcome :

Causality : Causality possible

Unknown

### Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Orthostatic hypotension		Orthostatic hypotension, body mass index increased and lack of drug effect.	
Body mass index increased			
Drug ineffective			

### Medicine details :

**CLOZARIL (Suspected)** Reason : Unspecified schizophrenia  
 Tablet 400 Milligram Daily Oral  
 Batch : Started : 15/12/2007 Stopped :

**SODIUM VALPROATE (Suspected)** Reason :  
 Batch : Started : Stopped :

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography				ECG revealed left anterior fascicular block, difficult to auscultate blood pressure, radial pulse poor volume,. troponin 1 increased, alkaline phosphatase increased and bilirubin increased.
Troponin	(<0.081 ug/L)	05/12/2007	1:0.09 ug/L	
Troponin	(<0.081 ug/L)	06/12/2007	1:0.09 ug/L	
Troponin	(<0.081 ug/L)	12/12/2007	1:0.09 ug/L	
Troponin	(<0.081 ug/L)	19/12/2007	1:0.09 ug/L	
Troponin	(<0.081 ug/L)	27/12/2007	1:0.08 ug/L	
Troponin	(<0.081 ug/L)	13/02/2008	1:0.08 ug/L	
Other data	(30-120 IU/L)	29/10/2007	136 IU/L	Alkaline phosphatase.
Other data	(30-120 IU/L)	13/02/2008	190 IU/L	Alkaline phosphatase.
Bilirubin		29/10/2007	136 umol/L	
Bilirubin		13/02/2008	22 umol/L	
Other data	(7-56 U/L)	18/10/2007	71	Alanine transaminase
Creatine phosphokinase	(0-5 mg/L)	15/10/2007	38.1	CRP

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase	(0-5 mg/L)	18/10/2007	17.5	CRP
Creatine phosphokinase	(0-5 mg/L)	29/10/2007	34	CRP
Albumin	(34-45 g/L)	15/10/2007	30	
Albumin	(34-45 g/L)	18/10/2007	30	
Albumin	(34-45 g/L)	29/10/2007	34	
Electrocardiography		14/08/2007	Left anterior fascicular block	
Electrocardiography		15/04/2007	Left anterior fascicular block	
Echocardiogram		14/12/2007	Borderline to mild increase in relative wall thickness and reduced tissue Doppler mitral annular velocities.	

# Public Case Detail

Cases Count: 393

**Case Number : 241101**

**Data Entry Date :** 22/05/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 02/05/2008  
**Outcome :**  
 Not yet recovered

**Gender :** M  
**Weight (kg) :** 66  
**Age :**  
**DOB :** 30/08/1976  
**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis	Life threatening	Myocarditis, myalgia, chest pain and feeling feverish.	Clopine ceased.
Chest pain	Life threatening		
Myalgia	Life threatening		
Pyrexia	Life threatening		
Tachycardia	Life threatening		

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
	75 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 21/04/2008	<b>Stopped :</b> 02/05/2008	
<b>OLANZAPINE (Other drug)</b>	<b>Reason :</b>		
	15 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Troponin		02/05/2008	0.12 (High)	
Erythrocyte sedimentation rate		02/05/2008	ESR raised	
White blood cells		02/05/2008	White count raised	
Other data		02/05/2008	Tachycardia 125	

# Public Case Detail

Cases Count: 393

**Case Number : 241142**

**Data Entry Date :** 23/05/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 30/04/2008  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :** 49Y  
**DOB :**  
**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Troponin increased	Caused or prolonged inpatient hospitalisation	Troponin rise.	Ceased Clozapine.

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
	125 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b> 09/04/2008	<b>Stopped :</b> 09/04/2008	
<b>DIAZEPAM (Other drug)</b>	<b>Reason :</b>		
	10 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	L TERM	<b>Stopped :</b>
<b>OLANZAPINE (Other drug)</b>	<b>Reason :</b>		
	30 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	L TERM	<b>Stopped :</b> 0

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Troponin		30/04/2008	0.26 mcg/L	
Troponin		29/04/2008	0.48 mcg/L	



# Public Case Detail

Cases Count: 393

**Case Number : 241383**

**Data Entry Date :** 30/05/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 26Y

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Pneumonia		pneumonia	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
	500 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 20/01/2006	<b>Stopped :</b> 01/05/2008	

# Public Case Detail

Cases Count: 393

**Case Number : 241467**

**Data Entry Date :** 02/06/2008

**Gender :** F

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Onset Date :** 09/04/2008

**Age :**

**DOB :** 11/04/1935

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome	Dantrolene

**Medicine details :**

<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
		75 Milligram	Daily
<b>Batch :</b>	<b>Started :</b>	S TERM	<b>Stopped :</b> 09/04/2008

# Public Case Detail

Cases Count: 393

**Case Number : 241508**

**Data Entry Date :** 03/06/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/04/2008

**Age :**

**DOB :** 19/05/1980

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Patient ceased Clopine treatment due to experiencing myocarditis.	Ceased Clopine

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
	25 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 11/04/2008	<b>Stopped :</b> 01/05/2008	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
White blood cells				The patient's white blood cell and neutrophil counts were generally elevated throughout treatment.

## Case Number : 241509

Data Entry Date : 03/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 08/04/2008

Age :

DOB : 02/11/1977

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient ceased Clopine treatment due to experiencing Myocarditis.	Ceased Clopine.

#### Medicine details :

**CLOPINE (Suspected)** Reason :  
200 Milligram Daily Oral  
Batch : Started : 25/03/2008 Stopped : 08/04/2008

**AMISULPRIDE (Other drug)** Reason :  
600 Milligram  
Batch : Started : Stopped :

**HALDOL DECANOATE (Other drug)** Reason :  
100 Milligram  
Batch : Started : Stopped :

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
ALT = SGPT		06/02/2008	376 U/L	
GGT = SGGT = GGTP		06/02/2008	102 U/L	
Ultrasound		26/02/2008	Normal	Upper abdominal ultrasound
Electrocardiography		07/04/2008	Sinus tachycardia	
Troponin		07/04/2008	0.40	
Troponin		08/04/2008	0.54	
Creatine kinase MB				Normal
Echocardiogram		08/04/2008	Abnormal (suggestion of some apico-septal, infero-septal and lateral hypokinesis)	

## Case Number : 241526

**Data Entry Date :** 03/06/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 06/05/2008  
**Outcome :**  
 Not yet recovered

**Gender :** M  
**Weight (kg) :** 68  
**Age :**  
**DOB :** 21/07/1979  
**Causality :** Causality possible

### Information:

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Alanine aminotransferase increased	Caused or prolonged inpatient hospitalisation	Increased ALT and AST	Ceased Clopine
Aspartate aminotransferase increased	Caused or prolonged inpatient hospitalisation		

### Medicine details :

<b>CLOZAPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
125 Milligram Daily Oral	
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>OLANZAPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
30 Milligram Daily Oral	
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>AMISULPRIDE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>DIAZEPAM (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>LORAZEPAM (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>THIAMINE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
ALT = SGPT		11/04/2008	303	?? May - ALT 509
ALT = SGPT		28/04/2008	58	?? May - ALT 509
ALT = SGPT		06/05/2008	470	?? May - ALT 509
AST = SGOT		11/04/2008	99	
AST = SGOT		06/05/2008	199	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
GGT = SGGT = GGTP		28/04/2008	52	

## Case Number : 241529

**Data Entry Date :** 03/06/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 06/05/2008  
**Outcome :**  
 Not yet recovered

**Gender :** M  
**Weight (kg) :** 68  
**Age :**  
**DOB :** 21/07/1979  
**Causality :** Causality possible

### Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Alanine aminotransferase increased	Caused or prolonged inpatient hospitalisation	Increased ALT and AST	Ceased Clozapine
Aspartate aminotransferase increased	Caused or prolonged inpatient hospitalisation		

### Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
100 Milligram Daily Oral	
<b>Batch :</b>	<b>Started :</b> 29/04/2008 <b>Stopped :</b>
<b>OLANZAPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
30 Milligram Daily Oral	
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>AMISULPRIDE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>DIAZEPAM (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>LORAZEPAM (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>THIAMINE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
ALT = SGPT		11/04/2008	303	?? May 08 - ALT 509
ALT = SGPT		28/04/2008	58	?? May 08 - ALT 509
ALT = SGPT		06/05/2008	470	?? May 08 - ALT 509
AST = SGOT		11/04/2008	99	
AST = SGOT		06/05/2008	199	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
GGT = SGGT = GGTP		28/04/2008	52	



# Public Case Detail

Cases Count: 393

**Case Number : 241542**

**Data Entry Date :** 04/06/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :**  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 16/08/1969  
**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Cellulitis	Caused or prolonged inpatient hospitalisation	Cellulitis and the infection becoming possibly septic.	Clopine ceased. Amitted to ICU.
Sepsis	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	650 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 12/11/2007	<b>Stopped :</b> 02/04/2008	

# Public Case Detail

Cases Count: 393

**Case Number : 241545**

**Data Entry Date :** 04/06/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 01/05/2008

**Age :**

**DOB :** 28/07/1939

**Outcome :** 01/05/2008

**Causality :** Causality possible

Unrelated death

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Death	Death	Death unexplained.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	250 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 30/01/2008	<b>Stopped :</b>	

## Case Number : 241562

Data Entry Date : 04/06/2008

Gender : F

Hospitalisation : Required a specialist consultation

Weight (kg) : 0

Onset Date : 20/04/2004

Age :

DOB : 13/07/1954

Outcome :

Causality : Causality possible

Unknown

Information: History of monocytosis and cough.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Leukopenia	Caused or prolonged inpatient hospitalisation	Leukopenia, neutropenia, thrombocytopenia, haematocrit decreased, monocytosis, cough and leukocytosis.	
Cough	Caused or prolonged inpatient hospitalisation		
Haematocrit decreased	Caused or prolonged inpatient hospitalisation		
Leukocytosis	Caused or prolonged inpatient hospitalisation		
Monocytosis	Caused or prolonged inpatient hospitalisation		
Neutropenia	Caused or prolonged inpatient hospitalisation		
Thrombocytopenia	Caused or prolonged inpatient hospitalisation		

### Medicine details :

CLOZARIL (Suspected)

Reason :

Tablet

300 Milligram

Daily

Oral

Batch :

Started : 18/09/2000

Stopped : 09/05/2008

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		18/09/2000	6.6x10 <sup>9</sup> /L	
Neutrophils		20/10/2004	0.70x10 <sup>9</sup> /L	
Neutrophils		27/12/2005	1.4x10 <sup>9</sup> /L	
Neutrophils		28/12/2008	1.52x10 <sup>9</sup> /L	
Neutrophils		30/12/2008	1.49x10 <sup>9</sup> /L	
Neutrophils		03/06/2006	3.61x10 <sup>9</sup> /L	

# Public Case Detail

Cases Count: 393

**Case Number : 241568**

**Data Entry Date :** 04/06/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 12/05/2008

**Age :**

**DOB :** 20/08/1974

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia and leucopenia.	Ceased Clopine
Leukopenia			

<b>Medicine details :</b>			
CLOPINE (Suspected)	Reason :		
Tablet	350 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 22/05/2006	<b>Stopped :</b>	12/05/2008

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		16/05/2008	3.30	
White blood cells		15/05/2008	2.80	
White blood cells		14/05/2008	3.20	
White blood cells		12/05/2008	5.00	
White blood cells		09/05/2008	4.60	
Neutrophils		16/05/2008	0.70	
Neutrophils		15/05/2008	0.70	
Neutrophils		14/05/2008	1.10	
Neutrophils		12/05/2008	1.20	
Neutrophils		09/05/2008	2.20	

## Case Number : 241585

Data Entry Date : 04/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 29/04/2008

Age :

DOB : 16/08/1958

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Splenomegaly	Caused or prolonged inpatient hospitalisation	Patient experienced mild splenomegaly, Troponin raised, borderline billirubin and low platelet count.	Clozaril discontinued.
Blood bilirubin abnormal	Caused or prolonged inpatient hospitalisation		
Eosinophil count increased	Caused or prolonged inpatient hospitalisation		
Heart rate increased	Caused or prolonged inpatient hospitalisation		
Lymphocyte count decreased	Caused or prolonged inpatient hospitalisation		
Myocarditis	Caused or prolonged inpatient hospitalisation		
Platelet count decreased	Caused or prolonged inpatient hospitalisation		
Salivary hypersecretion	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		
White blood cell count decreased	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

CLOZARIL (Suspected)

Reason : Unspecified schizophrenia

Tablet 100 Milligram Daily Oral

Batch : Started : 07/04/2008 Stopped : 29/04/2008 0

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Troponin		29/04/2008	0.27	
Troponin		01/05/2008	0.06	
Troponin		06/05/2008	0.48	
Bilirubin		29/04/2008	20	
Bilirubin		01/05/2008	-	
Bilirubin		06/05/2008	-	
Heart Rate		29/04/2008	-	
Heart Rate		01/05/2008	-	
Heart Rate		06/05/2008	136	

# Public Case Detail

Cases Count: 393

**Case Number : 241614**

**Data Entry Date :** 05/06/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 09/05/2008

**Age :**

**Outcome :** 09/05/2008

**DOB :** 17/01/1958

Death

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Death	Death	Male patient died due to unknown reasons whilst being treated with Clopine.	

<b>Medicine details :</b>			
<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	600 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 13/04/2006	L TERM	<b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 241625**

**Data Entry Date :** 05/06/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**Outcome :** 04/03/2008

**DOB :** 29/03/1981

Recovered

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Drug level increased		High clozapine levels.	Reducing clozapine.

**Medicine details :**

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	375 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 04/11/2002	<b>Stopped :</b>	

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Serum drug level		11/02/2008	1300	Clozapine level
Serum drug level		11/02/2008	560	Clozapine level
Serum drug level		11/02/2008	430	Clozapine level
Serum drug level		11/02/2008	380	Clozapine level



# Public Case Detail

Cases Count: 393

**Case Number : 241662**

**Data Entry Date :** 06/06/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 04/05/2008

**Age :**

**DOB :** 09/07/1934

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Neuroleptic malignant syndrome		switched from Clozapine to Clopine and experienced neuroleptic malignant syndrome	ceased drug

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
	150 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 07/02/2008	<b>Stopped :</b> 04/05/2008	

# Public Case Detail

Cases Count: 393

**Case Number : 241821**

**Data Entry Date :** 12/06/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 01/04/1966

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis.	

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	350 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 23/04/2008	<b>Stopped :</b> 09/05/2008	

# Public Case Detail

Cases Count: 393

**Case Number : 241822**

**Data Entry Date :** 12/06/2008

**Hospitalisation :**

**Onset Date :** 31/12/2007

**Outcome :**  
Unknown

**Gender :** M

**Weight (kg) :** 0

**Age :**

**DOB :** 01/03/1976

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy and ejection fraction decreased.	Clopine ceased.

<b>Medicine details :</b>			
CLOPINE (Suspected)		Reason :	
Tablet	600 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/03/2004	L TERM	<b>Stopped :</b> 01/04/2008

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Other data				Reduction in ejection fraction to 42%. Follow up cardiology review showed ejection fraction had improved to 59%.

# Public Case Detail

Cases Count: 393

**Case Number : 241836**

**Data Entry Date :** 12/06/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 12/05/2008  
**Outcome :**  
 Recovered

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 17/05/1977  
**Causality :** Causality possible

**Information:** Further information - Medical history included viral infection (? EBV), drug abuse (recreational use of tetrahydrocannabinol, cocaine, amphetamine), high HDL, obesity. The pt smoked 15 cigarettes per day.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest	Life threatening	Patient experienced a cardiac arrest and myocarditis.	Clozaril was discontinued.
Chest pain	Life threatening	Pt experienced chest pain - severe anterior, central sharp, stabbing in character and worse on deep inspiration - No change with posture, radiation; dyspnoea for 5 days. The chest pain was accompanied by vomiting. Pt's eosinophilic count , troponin T value and C-reactive proteins was increased. Pt was also prescribed zuclopenthixol depot (Clopixol) but was ceased because of extrapyramidal side effects. Pt later developed tachycardia	Clozaril was discontinued and risperidone initiated. Also was treated with atorvastatin and NSAID.
Akathisia	Life threatening		
C-reactive protein increased	Life threatening		
Cardiac arrest	Life threatening		
Eosinophil count increased	Life threatening		
Extrapyramidal disorder	Life threatening		
Musculoskeletal stiffness	Life threatening		
Myocarditis	Life threatening		
Pyrexia	Life threatening		
Sinus tachycardia	Life threatening		
Troponin T increased	Life threatening		
Vomiting	Life threatening		

## Medicine details :

CLOZARIL (Suspected)

Reason : Unspecified schizophrenia

300 Milligram Daily

Batch :

Started : 13/04/2008

Stopped : 12/05/2008

0

ZUCLOPENTHIXOL DECANOATE (Suspected)

Reason :

Batch :

Started :

Stopped :

ATORVASTATIN (Other drug)

Reason :

Batch :

Started :

Stopped :

RISPERIDONE (Other drug)

Reason :

Batch :

Started :

Stopped :

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				Normal with trivial physiological regurgitation and 42% left ventricular ejection fraction.
Chest X-ray				Essential segmental atelectasis right lower lobe.
C-Reactive Protein	<10	12/05/2008	152	High
C-Reactive Protein	<10	17/05/2008	74	High
Eosinophils	0.2 - 0.8 x 10 <sup>9</sup> /L	17/05/2008	1.34	High
Troponin	<0.02	12/05/2008	0.488	Troponin T - High
Troponin	<0.02	13/05/2008	0.529	Troponin T - High
Troponin	<0.02	14/05/2008	0.082	Troponin T - High
Troponin	<0.02	15/05/2008	0.05	Troponin T - High
Other data				EBV antibody was positive on 17 May 2008.

# Public Case Detail

Cases Count: 393

**Case Number : 241838**

**Data Entry Date :** 12/06/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 08/05/2008  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 22/06/1944  
**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Convulsion	Caused or prolonged inpatient hospitalisation	Patient experienced seizure.	Epilium and valproate.

<b>Medicine details :</b>	
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
	800 Milligram Daily
<b>Batch :</b>	<b>Started :</b> 13/07/2005 <b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 241990**

**Data Entry Date :** 17/06/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 16/05/2008

**Age :**

**Outcome :** 16/05/2008

**DOB :** 16/10/1965

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	Grand mal seizures.	Clozapine and fluoxetine withheld. Treated with intravenous diazepam 5mg.

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	600 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>FLUOXETINE HYDROCHLORIDE (Suspected)</b>		<b>Reason :</b> Depression	
Capsule	20 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	





# Public Case Detail

Cases Count: 393

**Case Number : 242043**

**Data Entry Date :** 18/06/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 31/03/1981

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** Current condition Diabetes (Diabetes mellitus); diagnosed prior to commencement of Clozaril.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Blood glucose increased		Patient experienced elevated blood sugar levels.	

## Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	12.5 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	S TERM	<b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 242056**

**Data Entry Date :** 18/06/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 22/05/2008

**Age :**

**DOB :** 09/08/1976

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Cardiomyopathy		Possible cardiomyopathy.	Ceased Clopine. Commenced Coversyl (perindopril) and metoprolol.

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
	450 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

## Case Number : 242058

**Data Entry Date :** 19/06/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 04/05/2008  
**Outcome :**  
 Recovered

**Gender :** F  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 09/07/1934  
**Causality :** Causality possible

### Information:

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Neuroleptic malignant syndrome: febrile, tachycardic, sweating, dystonic, rigidity	stopped: efexor, clopine, benztropine; treated with bromocriptine.

<b>Medicine details :</b>			
<b>BENZTROPINE MESYLATE (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b> 04/05/2008	0
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>EFEXOR (Suspected)</b>		<b>Reason :</b> Depression	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b> 04/05/2008	
<b>TRIMETHOPRIM (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b> 24/04/2008	<b>Stopped :</b> 05/05/2008	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Creatine phosphokinase		04/08/2008	2810	

# Public Case Detail

Cases Count: 393

**Case Number : 242110**

**Data Entry Date :** 19/06/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 16/05/2008

**Age :**

**DOB :** 18/07/1954

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Neutropenia and leucopenia	
Leukopenia			

<b>Medicine details :</b>			
CLOPINE (Suspected)	Reason :		
Tablet	350 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 14/01/2008	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		29/05/2008	2.60	
White blood cells		28/05/2008	2.70	
White blood cells		27/05/2008	2.60	
White blood cells		23/05/2008	2.70	
White blood cells		20/05/2008	2.50	
White blood cells		16/05/2008	2.60	
White blood cells		08/05/2008	3.50	
White blood cells		01/05/2008	4.90	
Neutrophils		29/05/2008	0.90	
Neutrophils		28/05/2008	0.90	
Neutrophils		27/05/2008	0.70	
Neutrophils		23/05/2008	0.60	
Neutrophils		20/05/2008	0.80	
Neutrophils		16/05/2008	1.50	
Neutrophils		08/05/2008	2.10	
Neutrophils		01/05/2008	3.00	

# Public Case Detail

Cases Count: 393

**Case Number : 242213**

**Data Entry Date :** 24/06/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 17/04/2008

**Age :**

**DOB :** 17/07/1974

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Suspected myocarditis.	Clopine ceased.

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	25 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 17/04/2008	<b>Stopped :</b>	30/04/2008

# Public Case Detail

Cases Count: 393

**Case Number : 242221**

**Data Entry Date :** 25/06/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/05/2008

**Age :**

**DOB :** 20/06/1983

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Myocarditis.	clopine ceased.

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 14/05/2008	<b>Stopped :</b> 21/05/2008	

# Public Case Detail

Cases Count: 393

**Case Number : 242226**

**Data Entry Date :** 25/06/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 22/05/2008

**Age :**

**DOB :** 30/09/1959

**Outcome :** 22/05/2008

**Causality :** Causality possible

Unrelated death

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Death	Death	Death unexplained.	

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 31/05/2004	<b>Stopped :</b> 22/05/2008	

# Public Case Detail

Cases Count: 393

**Case Number : 242243**

**Data Entry Date :** 25/06/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Gender :** F

**Weight (kg) :** 0

**Age :**

**DOB :** 15/08/1939

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
White blood cell count increased		White cell and neutrophil counts were elevated.	Ceased Clopine
Neutrophil count increased			
Pneumonia			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 06/02/2008	<b>Stopped :</b>	02/06/2008

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		03/06/2008	15.25	x 10 <sup>9</sup> /L
White blood cells		06/05/2008	13.00	x 10 <sup>9</sup> /L
Neutrophils		03/06/2008	12.60	10 <sup>9</sup> /L
Neutrophils		06/05/2008	9.40	10 <sup>9</sup> /L



# Public Case Detail

Cases Count: 393

**Case Number : 242245**

**Data Entry Date :** 25/06/2008

**Gender :** M

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Onset Date :** 01/06/2008

**Age :**

**DOB :** 21/08/1981

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient developed a temperature (38C), tachycardia and hypotension. A transthoracic echocardiogram (TTE) showed decreased left ventricular function. The patient was diagnosed with clozapine induced myocarditis.	Clopine ceased.

**Medicine details :**

<b>CLOZAPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	300 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 19/05/2008 <b>Stopped :</b> 01/06/2008
<b>LITHIUM CARBONATE (Other drug)</b>	<b>Reason :</b>
	1.8 Milligram Daily
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 242247**

**Data Entry Date :** 25/06/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 22/05/2008  
**Outcome :**  
 Not yet recovered

**Gender :** F  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 19/08/1982  
**Causality :** Causality certain

**Information:** Cert:rechall  
 Commenced Clopine again on 13 Dec 2008 and experienced myocarditis again.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Suspected early myocarditis.	Ceased clopine.

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	300 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 03/05/2008 <b>Stopped :</b> 22/05/2008
<b>AMISULPRIDE (Other drug)</b>	<b>Reason :</b>
	700 Milligram Daily
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>QUETIAPINE (Other drug)</b>	<b>Reason :</b>
	300 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				Relevant tests: 22/05/08 - Troponin 0.07;
				??/05/08 - Troponin <0.05 (Normal)
				22/05/08 - Cardiac Exam NAD
				??/05/08 - Echocariogram Normal

# Public Case Detail

Cases Count: 393

**Case Number : 242252**

**Data Entry Date :** 25/06/2008

**Gender :** F

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Onset Date :** 03/06/2008

**Age :**

**DOB :** 25/02/1979

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Eosinophilia	Caused or prolonged inpatient hospitalisation	Eosinophillia and increased white blood cell levels and neutrophil counts.	
Neutrophil count increased	Caused or prolonged inpatient hospitalisation		
White blood cell count increased	Caused or prolonged inpatient hospitalisation		

**Medicine details :**

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	150 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 22/04/2008	<b>Stopped :</b>	

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Neutrophils	7.7-1.8 x10 <sup>9</sup> /L			Neutrophil count increased High 9.3 x 10(9)/L
White blood cells	11.0 - 4.5 x 10 <sup>9</sup> /L			19.3 x 10 <sup>9</sup> /L
Eosinophils				High - 1.4 x 10 <sup>9</sup> /L

## Case Number : 242254

Data Entry Date : 25/06/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 20/05/1955

Outcome :

Causality : Causality possible

Recovered

### Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Platelet count increased		Platelet count increased.	Clozaril discontinued

### Medicine details :

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	275 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 25/10/2007 <b>Stopped :</b> 28/11/2007
<b>BENZTROPINE MESYLATE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> 15/05/2007 <b>Stopped :</b>
<b>CLONAZEPAM (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>MORPHINE NOS (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>THIORIDAZINE HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> 15/03/2007 <b>Stopped :</b> 10/11/2007
<b>VENLAFAXINE HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> 15/04/2006 <b>Stopped :</b>

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Platelets		19/11/2007	466 x 10 <sup>9</sup> /L	
Platelets		28/11/2007	611 x 10 <sup>9</sup> /L	
Platelets		29/11/2007	599 x 10 <sup>9</sup> /L	
Platelets		13/12/2007	329 x 10 <sup>9</sup> /L	
Platelets		21/12/2007	258 x 10 <sup>9</sup> /L	
Platelets		14/01/2008	267 x 10 <sup>9</sup> /L	

# Public Case Detail

Cases Count: 393

**Case Number : 242259**

**Data Entry Date :** 25/06/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 05/04/1974

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Hepatic necrosis		Tired, red, raised, scaly rash - almost psoriatic, hepatic necrosis.	
Fatigue			
Rash			
Rash erythematous			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 242261**

Data Entry Date : 25/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 27/06/1935

Outcome :

Causality : Causality possible

Not yet recovered

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Hypotension		Hypotension	Clozaril discontinued.

<b>Medicine details :</b>			
<b>ASPIRIN (Suspected)</b>		<b>Reason :</b>	
	150 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>CLOZARIL (Suspected)</b>		<b>Reason : Unspecified schizophrenia</b>	
Tablet	50 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started : 14/04/2008</b>	<b>Stopped : 02/05/2008</b>	
<b>AMLODIPINE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>CARBAMAZEPINE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>DIAZEPAM (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>METFORMIN HYDROCHLORIDE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>PERINDOPRIL (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>THYROXINE SODIUM (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 242295**

**Data Entry Date :** 25/06/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 24/04/2006

**Age :**

**DOB :** 12/06/1981

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Hepatic function abnormal		"Really raised GGT, ALT and AST", fever.	
Protein total increased			
Pyrexia			

**Medicine details :**

**CLOZARIL (Suspected)** Reason : Unspecified schizophrenia  
 Tablet 300 Milligram Daily Oral

Batch : Started : 03/04/2006 Stopped :

**OLANZAPINE (Other drug)** Reason :

Batch : Started : Stopped :

**SODIUM VALPROATE (Other drug)** Reason :

Batch : Started : Stopped :

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
ALT = SGPT				High - 101
AST = SGOT				High - 54
GGT = SGGT = GGTP				371
Protein				High - 92

## Case Number : 242311

Data Entry Date : 26/06/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 07/04/2008

Age :

DOB : 16/01/1970

Outcome :

Causality : Causality possible

Death

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Death	Death	Patient complained of having recent onset of seizures. His GP thought these were due to postural hypotension. Patient had been on treatment with clozapine from 02 Aug 2000 and switched to Clopine Brand on 25 March 2008. He died during his sleep on 07April 2008 . Death is unexplained; father of patient attributes it to seizures.	
Convulsion	Death		

#### Medicine details :

<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
	400	Daily	Oral
<b>Batch :</b>	<b>Started : 25/03/2000</b>	<b>Stopped : 06/04/2008</b>	
<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b>	
	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started : 02/08/2000</b>	<b>Stopped : 24/03/2008</b>	

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells				



# Public Case Detail

Cases Count: 393

**Case Number : 242333**

**Data Entry Date :** 26/06/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 02/10/1974

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Myocarditis	Ceased Clopine

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 09/05/2008	<b>Stopped :</b> 26/05/2008	

# Public Case Detail

Cases Count: 393

**Case Number : 242337**

**Data Entry Date :** 27/06/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 23/01/1973

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Convulsion		Seizures while on Clopine.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	500 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 19/03/2008	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 242352**

**Data Entry Date :** 27/06/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 04/05/2008

**Age :**

**DOB :** 08/10/1991

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Chest pain		Chest pain and hypotension.	
Bundle branch block bilateral	Caused or prolonged inpatient hospitalisation		
Dizziness	Caused or prolonged inpatient hospitalisation		
Electrocardiogram QT prolonged	Caused or prolonged inpatient hospitalisation		
Hypotension			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Schizophrenia	
Tablet	125 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0

# Public Case Detail

Cases Count: 393

**Case Number : 242377**

**Data Entry Date :** 30/06/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 19/05/2008

**Age :**

**DOB :** 27/03/1974

**Outcome :** 20/05/2008

**Causality :** Causality probable

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Myocarditis.	Clopine ceased.

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason : Unspecified schizophrenia</b>		
Tablet	50 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 17/05/2008	<b>Stopped :</b> 19/05/2008	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Troponin		19/05/2008	0.08 U/L	Troponin
C-Reactive Protein		19/05/2008	83 M/G/L	CRP
Creatine phosphokinase		19/05/2008	Normal	CK
Temperature		19/05/2008	38.5c	Fever

**Case Number : 242386**

**Data Entry Date :** 30/06/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 25/05/2008

**Age :**

**DOB :** 18/06/1966

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Convulsion		seizure	
Unresponsive to stimuli			

**Medicine details :**

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
500 Milligram Daily Oral	
<b>Batch :</b>	<b>Started :</b> 03/01/1996 <b>Stopped :</b>
<b>BENZTROPINE MESYLATE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>LACTULOSE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>MULTIVITAMINS (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>PROPRANOLOL HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>SODIUM VALPROATE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 242509**

**Data Entry Date :** 01/07/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 09/06/2008

**Age :**

**DOB :** 18/12/1976

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Pericarditis		Patient suffered from cardiac complications - pericarditis/myocarditis.	
Myocarditis			
Neutrophil count decreased			
White blood cell count decreased			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 24/05/2008	<b>Stopped :</b> 09/06/2008	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Neutrophils		17/05/2008	5.5*10 <sup>9</sup>	
Neutrophils		07/06/2008	3.5*10 <sup>9</sup>	
White blood cells		17/05/2008	7.7*10 <sup>9</sup>	
White blood cells		07/06/2008	4.60*10 <sup>9</sup>	

# Public Case Detail

Cases Count: 393

**Case Number : 242691**

**Data Entry Date :** 08/07/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 10/10/1972

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** The patient's white blood cell counts and neutrophil counts were within normal ranges throughout treatment.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced myocarditis.	Ceased Clopine.

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>	
Tablet	1 Dose Unspec Daily	Oral
<b>Batch :</b>	<b>Started :</b> 23/04/2008	<b>Stopped :</b> 10/05/2008

# Public Case Detail

Cases Count: 393

**Case Number : 242695**

**Data Entry Date :** 08/07/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 20/06/2008

**Age :**

**DOB :** 06/10/1982

**Outcome :**

**Causality :** Causality probable

Not yet recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced severe neutropenia and moderate leucopenia whilst being treated with Clopine.	Clopine ceased.
Leukopenia			

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
Tablet	200 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 10/05/2007 <b>Stopped :</b> 20/06/2008

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
White blood cells		22/06/2008	3.00	(X10 <sup>9</sup> /L)
White blood cells		20/06/2008	2.10	(X10 <sup>9</sup> /L)
White blood cells		30/05/2008	4.10	(X10 <sup>9</sup> /L)
Neutrophils		22/06/2008	2.01	(X10 <sup>9</sup> /L)
Neutrophils		20/06/2008	0.80	(X10 <sup>9</sup> /L)
Neutrophils		30/05/2008	2.60	(X10 <sup>9</sup> /L)
Serum drug level		22/06/2008	0.0	(MG)
Serum drug level		20/06/2008	0.0	(MG)
Serum drug level		30/05/2008	200.0	(MG)



# Public Case Detail

Cases Count: 393

**Case Number : 242820**

**Data Entry Date :** 11/07/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :**  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 08/01/1974  
**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Urinary tract infection	Caused or prolonged inpatient hospitalisation	Patient developed a "urinary sepsis".	Withheld Clopine for 2 days and recommenced on the 12/06/2008 at a dose of 12.5mg/daily.

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	700 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 07/06/2006	<b>Stopped :</b>	0

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		17/06/2008	9.03 x10 <sup>9</sup> /L	WCC
White blood cells		12/06/2008	20.00	WCC
Neutrophils		17/06/2008	6.47 x 10 <sup>9</sup> /L	Neut - MG = 125.0 and 12.5
Neutrophils		12/06/2008	16.28	Neut - MG = 125.0 and 12.5

# Public Case Detail

Cases Count: 393

**Case Number : 242851**

**Data Entry Date :** 11/07/2008

**Gender :** F

**Hospitalisation :** Required a specialist consultation

**Weight (kg) :** 67

**Onset Date :**

**Age :**

**DOB :** 11/08/1972

**Outcome :** 29/04/2008

**Causality :** Causality probable

Recovered

**Information:** The patient's white cell and neutrophil counts were within the normal ranges throughout treatment.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Tachycardia	Caused or prolonged inpatient hospitalisation	Tachycardia and ST segment depression.	Treated with metoprolol. Clopine dose reduced.
Electrocardiogram ST segment depression	Caused or prolonged inpatient hospitalisation		

## Medicine details :

**CLOZAPINE (Suspected)**

**Reason :**

Tablet

450 Milligram

Daily

Oral

**Batch :**

**Started :** 03/03/2006

**Stopped :**

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				Repeat echocardiogram, which was normal. Cardiac enzymes were also normal.

# Public Case Detail

Cases Count: 393

## Case Number : 243028

Data Entry Date : 18/07/2008

Hospitalisation :

Onset Date : 11/08/2006

Outcome :  
Unknown

Gender : M

Weight (kg) : 0

Age :

DOB : 12/11/1967

Causality : Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		This patient was taking Clozaril for an unspecified indication and had discontinued and recommenced treatment five times since 15/06/1999.	Clozaril was discontinued and was being re-started at the time of the report.

#### Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	600 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 16/10/2003	<b>Stopped :</b>	

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				Patient's annual echo showed mild global hypokinesia with Clozaril cardiomyopathy.

# Public Case Detail

Cases Count: 393

**Case Number : 243196**

**Data Entry Date :** 24/07/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 01/10/1965

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** White blood cell and neutrophil counts were within normal ranges for the treatment period.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy	Clopine ceased.

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 17/01/2007	<b>Stopped :</b> 06/06/2008	

## Case Number : 243208

**Data Entry Date :** 24/07/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 16/03/2008  
**Outcome :**  
 Recovered

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 25/07/1971  
**Causality :** Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Dizziness	Caused or prolonged inpatient hospitalisation	Myocarditis secondary to Clozapine.	All meds ceased.
Chest discomfort	Caused or prolonged inpatient hospitalisation		
Myocarditis	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		
Troponin increased	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

<b>CLOZAPINE (Suspected)</b>	<b>Reason :</b>
Tablet	125 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 03/03/2008 <b>Stopped :</b> 16/03/2008
<b>FLUPENTHIXOL DECANOATE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>LITHIUM CARBONATE (Other drug)</b>	<b>Reason :</b>
	500 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b> 16/03/2008
<b>OLANZAPINE (Other drug)</b>	<b>Reason :</b>
	20 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b> 16/03/2008
<b>SERTRALINE HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>
	50 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 19/02/2008 <b>Stopped :</b>

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				17/03/08 - temperature was 37-39 C, tachy = 110. troponin = 01.31, K= =3.9. Na+ =134, creatinine = 68 on 16/03/08

## Case Number : 243338

**Data Entry Date :** 30/07/2008

**Gender :** F

**Hospitalisation :** Treated in Accident/Emergency Depar

**Weight (kg) :** 0

**Onset Date :**

**Age :** 34Y

**Outcome :**

**DOB :**

Recovered

**Causality :** Causality probable

**Information:** History of bizarre behaviour and auditory hallucinations. 24d. Report Source Literature. Journal: Australian and New Zealand Journal of Psychiatry. Author: Caetano D, Gandhi C. Title: Clozapine-induced myocarditis. Volume: 42(5) Year: 2008. Pages: 434-435.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient developed myocarditis, electrocardiogram QT prolonged, tachycardia, pyrexia, white blood cell count increased, C-reactive protein increased, troponin T increased, eosinophil count increased, nausea and dizziness.	Clozapine ceased.
C-reactive protein increased			
Dizziness			
Electrocardiogram QT prolonged			
Eosinophil count increased			
Nausea			
Neutrophil count increased			
Pyrexia			
Red blood cell sedimentation rate increased			
Tachycardia			
Troponin I increased			
Troponin T increased			
White blood cell count increased			

### Medicine details :

**CLOZAPINE (Suspected)**

**Reason :** Unspecified schizophrenia

Tablet 125 Milligram Daily Oral

**Batch :**

**Started :**

**Stopped :**

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Blood culture	70			Blood creatine phosphokinase 54IU/l week 2 + 4 days of clozapine treatment.

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
C-Reactive Protein	10			C-reactive protein high week 2 + 4 days of clozapine treatment. 117.8 mg/L. C-reactive protein high at emergency department. 98 mg/L
Electrocardiography				Electrocardiogram QT interval baseline 428. Electrocardiogram QT interval week 2 of clozapine treatment 506. Electrocardiogram QT interval week 2 + 4 days of clozapine treatment 503.
Neutrophils				Neutrophil count week 2 + 4 days of clozapine treatment $9.6 \times 10^9$ .
Red blood cells	20			Red blood cell sedimentation rate week 2 + 4 days of clozapine treatment 81 mm/h
Troponin	0.05			Troponin I 0.243. Troponin T at emergency department.
Other data				Test/assessment/notes week 2 + 4 days of clozapine treatment.
White blood cells				White blood cell count week 2 + 4 days of clozapine treatment $12.1 \times 10^9$ . White blood cell count at emergency department $10.9 \times 10^9$ .



## Case Number : 243376

**Data Entry Date :** 31/07/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 04/06/2008  
**Outcome :** 18/06/2008  
 Recovered

**Gender :** M  
**Weight (kg) :** 113  
**Age :**  
**DOB :** 17/10/1948  
**Causality :** Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Acute myocardial infarction	Caused or prolonged inpatient hospitalisation	Acute myocardial infarction	Coronary artery bypass graft

#### Medicine details :

**CLOPINE (Suspected)** Reason : Unspecifid affective psychosis

Tablet 300 Milligram Daily Oral

Batch : Started : Stopped :

**CLOZARIL (Suspected)** Reason : Unspecifid affective psychosis

Oral

Batch : Started : 30/03/1995 Stopped : 07/06/2008

**ASPIRIN (Other drug)** Reason :

Batch : Started : Stopped :

**ATORVASTATIN (Other drug)** Reason :

Batch : Started : Stopped :

**BENZTROPINE MESYLATE (Other drug)** Reason :

Batch : Started : Stopped :

**METFORMIN HYDROCHLORIDE (Other drug)** Reason :

Batch : Started : Stopped :

**METOPROLOL TARTRATE (Other drug)** Reason :

Batch : Started : Stopped :

**PROTAPHANE (Other drug)** Reason :

Batch : Started : Stopped :

**RAMIPRIL (Other drug)** Reason :

Batch : Started : Stopped :

**Medicine details :**

VENLAFAXINE HYDROCHLORIDE (Other drug)

Reason :

Batch :

Started :

Stopped :  

---

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Coronary angiogram				It was found that the patient had normal left ventricular contraction with ejection fraction of less than 60%. No stenosis in the left main coronary artery, diffuse moderate disease with focal stenosis of 90% proximal left anterior descending, left circumflex 95% proximal stenosis, right coronary artery mild diffuse irregularities with focal stenosis 80%.

# Public Case Detail

Cases Count: 393

**Case Number : 243389**

**Data Entry Date :** 01/08/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 01/07/2008

**Age :**

**DOB :** 24/04/1966

**Outcome :**

**Causality :** Causality certain

Not yet recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Neutropenia		Patient experienced severe neutropenia and moderate leucopenia whilst being treated with Clopine.	Clopine ceased 01/07/08
Leukopenia			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	175 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 05/06/2001	<b>Stopped :</b> 01/06/2008	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
White blood cells		04/07/2008	4.00	
White blood cells		03/07/2008	3.80	
White blood cells		02/07/2008	2.40	
White blood cells		01/07/2008	2.30	
White blood cells		04/06/2008	5.70	
Neutrophils		04/07/2008	1.50	
Neutrophils		03/07/2008	1.30	
Neutrophils		02/07/2008	1.00	
Neutrophils		01/07/2008	0.90	
Neutrophils		04/06/2008	3.00	

# Public Case Detail

Cases Count: 393

**Case Number : 243393**

**Data Entry Date :** 01/08/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 19/06/2008

**Age :**

**DOB :** 01/06/1989

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Loss of consciousness		Patient took an overdose of Clopine and was found unconscious on 19/06/08.	
Intentional overdose			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	500 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 28/11/2007	<b>Stopped :</b>	30/04/2008

# Public Case Detail

Cases Count: 393

**Case Number : 243396**

**Data Entry Date :** 01/08/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**Outcome :**

**DOB :** 14/08/1965

Unknown

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Convulsion		The patient commenced treatment with Clozapine on 12/09/1994 and was switched to Clopine brand on 05/02/04. He was titrated up to PO 800mg daily, but was taking 300mg PO daily around the time of the event. On an unknown date in 2008, the patient experienced seizures and pinpoint pupils and was reported to be delirious. It was suspected that the patient had taken an overdose of Clopine. It was also noted that the patient was non-compliant.	
Delirium			
Overdose			

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
Tablet	300 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 05/02/2004 <b>Stopped :</b>

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Other data				The patient's white cell and neutrophil counts were within normal ranges for the treatment period with the exception of a few slightly raised counts on occasion.

# Public Case Detail

Cases Count: 393

**Case Number : 243422**

**Data Entry Date :** 01/08/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 19/07/2008

**Age :**

**DOB :** 29/06/1987

**Outcome :** 19/07/2008

**Causality :** Causality probable

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Chest pain		Patient complained of chest pain. T wave inversion.	
Electrocardiogram T wave inversion			

<b>Medicine details :</b>			
<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b>	
	200 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b> 01/07/2008	<b>Stopped :</b> 19/07/2008	

# Public Case Detail

Cases Count: 393

**Case Number : 243427**

**Data Entry Date :** 01/08/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 15/09/1962

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Ceased Clopine treatment due to experiencing myocarditis.	Ceased Clopine

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	250 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 29/05/2008	<b>Stopped :</b> 09/07/2008	

# Public Case Detail

Cases Count: 393

**Case Number : 243428**

**Data Entry Date :** 01/08/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 29/06/1947

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Convulsion		Patient ceased Clopine treatment due to seizures.	Ceased Clopine

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	650 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	L TERM	<b>Stopped :</b> 0



# Public Case Detail

Cases Count: 393

## Case Number : 243429

Data Entry Date : 01/08/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 25/06/2008

Age :

DOB : 26/02/1959

Outcome : 25/06/2008

Causality : Causality probable

Recovered

### Information:

Reaction :			
Preferred Term	Severity	Report Description	Treatment
Myocarditis		Ceased Clopine treatment due to experiencing myocarditis.	Ceased Clopine

Medicine details :			
CLOPINE (Suspected)		Reason : Unspecified psychosis	
Tablet	225 Milligram	Daily	Oral
Batch :	Started : 02/06/2008	Stopped :	25/06/2008

Laboratory Investigations :				
Type	Range	Date Tested	Result	Details
Creatine kinase MB		25/06/2008	Elevated	
Troponin		25/06/2008	Abnormal	

## Case Number : 243540

Data Entry Date : 06/08/2008

Hospitalisation :

Onset Date : 09/05/2008

Outcome :  
Recovered

Gender : F

Weight (kg) : 0

Age :

DOB : 01/04/1966

Causality : Causality probable

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Became febrile 38.2 degrees, with sinus tachycardia	Ceased Clozapine and Quetiapine dose increased to 200mg nocte.

#### Medicine details :

<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	10/05/2008 0
<b>QUETIAPINE (Other drug)</b>		<b>Reason :</b> Unspecified schizophrenia	
	100 Milligram	Total	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>ZUCLOPENTHIXOL ACETATE (Other drug)</b>		<b>Reason :</b>	
Injection	300 Milligram		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
	09/05/2008		

# Public Case Detail

Cases Count: 393

**Case Number : 243613**

**Data Entry Date :** 07/08/2008

**Gender :** M

**Hospitalisation :** Treated in outpatient department only.

**Weight (kg) :** 0

**Onset Date :**

**Age :** 53Y

**Outcome :**

**DOB :**

Not yet recovered

**Causality :** Causality certain

**Information:** Cert (Rechall)

Three weeks after the commencement of Clozapine with concurrent laxative administration, the patient developed a further episode of severe constipation with faecal impaction.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Abdominal pain	Treated in outpatient department only	53 year old single Caucasian male who presented to the emergency department with severe abdominal pain and bilious vomiting. On examination in emergency department, patient was drowsy, sweaty, afebrile, tachycardic and hypotensive. His abdomen was distended and he had severe generalised abdominal pain. His vomitus was bilious and had an offensive odour. Olanzapine and lithium were gradually re-introduced after 10 days as he showed signs of a relapse of his schizoaffective disorder. Clozapine was gradually re-introduced and increased to a dose of 350 mg/day in two divided doses.	Manual bowel disimpaction was performed. All his medications were ceased. Lactulose and docusate sodium (coloxyl with senna) were prescribed concurrently in liason with a gastroenterologist. The clozapine was ceased. His normal bowel movements resumed after several fleet enemas. He was commenced on risperidone 2mg once a day. The patient continues to be thought-disordered with elevated mood. He requires a weekly fleet enema.
Abdominal distension	Treated in outpatient department only		
Hyperhidrosis	Treated in outpatient department only		
Hypotension	Treated in outpatient department only		
Intestinal dilatation	Treated in outpatient department only		
Somnolence	Treated in outpatient department only		
Tachycardia	Treated in outpatient department only		
Vomiting	Treated in outpatient department only		

## Medicine details :

### CLOZAPINE (Suspected)

Reason : Unspecified schizophrenia

Tablet 700 Milligram Daily Oral

Batch : Started : Stopped :

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### IRON ORAL NOS (Other drug)

Reason :

Batch : Started : Stopped :

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### LITHIUM CARBONATE (Other drug)

Reason :

500 Milligram Daily

Batch : Started : Stopped :

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### MULTIVITAMINS (Other drug)

Reason :

Batch : Started : Stopped :

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### OLANZAPINE (Other drug)

Reason :

20 Milligram Daily

Batch : Started : Stopped :

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### RISPERIDONE (Other drug)

Reason :

Batch : Started : Stopped :

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## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				His investigations revealed a raised white cell count with normal urea, electrolytes and liver function tests. His blood gases showed metabolic acidosis. The abdominal x-ray revealed multiple fluid levels and faecal loading mainly in his large bowel. The computed tomography scan similarly showed that his transverse and descending colon was loaded with faeces until the rectum, with no evidence of a mechanical obstruction. He was diagnosed with sepsis due to faecal impaction. Urgent exploratory laparotomy revealed severely impacted faeces in the large and small bowel.

# Public Case Detail

Cases Count: 393

**Case Number : 243846**

**Data Entry Date :** 15/08/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/07/2008

**Age :**

**Outcome :** 30/07/2008

**DOB :** 15/12/1971

Recovered

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Patient ceased treatment with Clopine due to myocarditis.	Ceased Clopine

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	1 Dose Unspec	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Troponin	<0.03			troponin peaked at 3.20.
Magnetic Resonance Imaging				MRI heart scan consistent with myocarditis and elevated CK.

# Public Case Detail

Cases Count: 393

**Case Number : 243847**

**Data Entry Date :** 15/08/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 22/07/2008

**Age :**

**DOB :** 03/06/1980

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Neutropenia		Patient ceased treatment with Clopine due to severe neutropenia and severe leucopenia.	Ceased Clopine
Leukopenia			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	150 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
White blood cells		24/07/2008	2.80	
White blood cells		23/07/2008	2.10	
White blood cells		22/07/2008	1.70	
White blood cells		24/06/2008	3.80	
Neutrophils		24/07/2008	0.80	
Neutrophils		23/07/2008	0.70	
Neutrophils		22/07/2008	0.60	
Neutrophils		24/06/2008	2.40	

## Case Number : 243849

**Data Entry Date :** 15/08/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 23/06/2008  
**Outcome :**  
 Recovered

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 23/12/1969  
**Causality :** Causality certain

**Information:** CERT (rechall)  
 Rechallenged on Clozapine starting on 30/7/08 but developed high grade fever again and Clozapine stopped accordingly.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Patient developed high grade fever after commencing on Clozapine. Titrated from 25mg daily up to 350 mg daily from 23/6/08 to 2/7/08.	Clozapine stopped permanently

### Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
350 Milligram Daily	
<b>Batch :</b>	<b>Started :</b> 23/06/2008 <b>Stopped :</b> 02/07/2008
<b>AMISULPRIDE (Other drug)</b>	<b>Reason :</b>
400 Milligram	
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>EPILIM (Other drug)</b>	<b>Reason :</b> Other&unspecified epilepsy
1000 Milligram Daily	
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>SEROQUEL (Other drug)</b>	<b>Reason :</b> Unspecified schizophrenia
800 Milligram Daily	
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>THYROXINE SODIUM (Other drug)</b>	<b>Reason :</b> Myxedema
100 Milligram Daily	
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 244025**

**Data Entry Date :** 21/08/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 21/07/2008

**Age :**

**DOB :** 10/04/1941

**Outcome :** 27/07/2008

**Causality :** Causality possible

Recovered with sequelae

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Leukopenia		Severe reduction in WCC and differentials (agranulocytosis). Resulted in slow recovery.	Ceasation of Clozapine
Agranulocytosis			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet		1 time	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b> 21/07/2008	0



# Public Case Detail

Cases Count: 393

**Case Number : 244054**

**Data Entry Date :** 21/08/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 02/04/2008

**Age :**

**DOB :** 15/05/1952

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Somnambulism		sleep walking	dose reduced to 600 mg on 2/4/08 - sleep walking ceased after dose reduction

<b>Medicine details :</b>			
<b>CLOZAPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	700 Milligram	Oral	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 244169**

**Data Entry Date :** 26/08/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 30/07/1955

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** The patient's white cell and neutrophil counts were within normal limits for the treatment period

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced myocarditis.	Clopine ceased.

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	175 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 12/06/2008	<b>Stopped :</b> 04/07/2008	

# Public Case Detail

Cases Count: 393

**Case Number : 244218**

**Data Entry Date :** 28/08/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 12/08/2008

**Age :**

**DOB :** 03/07/1975

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Neutropenia		Neutropenia.	
Hepatitis C			
Lymphocytosis			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
		800 Milligram	Daily
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	12/08/2008

# Public Case Detail

Cases Count: 393

**Case Number : 244231**

**Data Entry Date :** 28/08/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 11/08/2008

**Age :**

**DOB :** 22/02/1970

**Outcome :** 11/08/2008

**Causality :** Causality possible

Death

**Information:** Further information received - Medical history: Pt had h/o COPD and polycythaemia. The cause of death was related to underlying disease.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocardial infarction	Death	Patient experienced a myocardial infarction and died whilst being treated with Clopine.	

## Medicine details :

<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	600 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 29/05/2006	<b>Stopped :</b> 11/08/2008	
<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	600 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 19/10/1994	<b>Stopped :</b> 29/05/2006	
<b>RISPERIDONE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
	1 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b> 09/08/2008	0

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				The patient's white cell count and neutrophil counts were generally within the normal ranges throughout.

## Case Number : 244340

Data Entry Date : 03/09/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age : 33Y

Outcome :

DOB :

Recovered

Causality : Causality possible

**Information:** Floreani J, Bastiampillai T. Successful re-challenge with clozapine following development of clozapine-induced cardiomyopathy. Australian & New Zealand Journal of Psychiatry. Aug 2008, 42 (8): 747-748.  
Other: Medically Important: Required Intervention.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Clozapine induced cardiomyopathy	ACE-I, ramipril 5mg, digoxin 250ug, carvedilol

### Medicine details :

CLOZAPINE (Suspected)	Reason : Unspecified schizophrenia	
Batch :	Started :	Stopped :

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram				In December 2004, a routine echo indicated a mildly dilated left ventricle (LV) with mild LV dysfunction and ejection fraction (EF) 45-90%. On cardiology review, the diagnosis was made of probable mild cardiomyopathy. A repeat echocardiogram 6 months later demonstrated a significant worsening of his LV function, with EF 35-40% and increased LV dilatation.

## Case Number : 244349

Data Entry Date : 03/09/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 29/07/2008

Age :

DOB : 14/02/1976

Outcome :

Causality : Causality possible

Not yet recovered

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced severe neutropenia and leucopenia.	
Leukopenia			

#### Medicine details :

CLOPINE (Suspected)		Reason :	
Tablet	700 Milligram	Daily	Oral
Batch :	Started :	L TERM	Stopped :

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		30/06/2008	3.70	
White blood cells		28/07/2008	2.50	
White blood cells		29/07/2008	2.00	
White blood cells		30/07/2008	2.50	
White blood cells		31/07/2008	1.70	
White blood cells		01/08/2008	2.10	
White blood cells		02/08/2008	1.60	
White blood cells		03/08/2008	2.80	
White blood cells		04/08/2008	1.80	
White blood cells		05/08/2008	1.70	
White blood cells		06/08/2008	2.00	
Neutrophils		30/06/2008	2.20	
Neutrophils		28/07/2008	1.10	
Neutrophils		29/07/2008	0.80	
Neutrophils		30/07/2008	1.70	
Neutrophils		31/07/2008	0.80	
Neutrophils		01/08/2008	0.90	
Neutrophils		02/08/2008	0.80	
Neutrophils		03/08/2008	1.20	
Neutrophils		04/08/2008	0.90	
Neutrophils		05/08/2008	0.90	

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Neutrophils		06/08/2008	1.20	

# Public Case Detail

Cases Count: 393

**Case Number : 244350**

**Data Entry Date :** 03/09/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/07/2008

**Age :**

**DOB :** 25/12/1982

**Outcome :** 18/07/2008

**Causality :** Causality possible

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Patient developed myocarditis.	Ceased Clopine

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 20/06/2008	<b>Stopped :</b>	17/07/2008



# Public Case Detail

Cases Count: 393

**Case Number : 244352**

**Data Entry Date :** 03/09/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 23/12/1969

**Outcome :**

**Causality :** Causality certain

Recovered

**Information:** Cert(rechall)

Patient recommenced Clopine and developed same symptoms.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Pyrexia		Patient developed rigors, fever up to 41.5 degrees C and felt unwell.	Ceased Clopine
Chills			
Dizziness			

## Medicine details :

CLOPINE (Suspected)		Reason : Unspecified schizophrenia	
Tablet	350 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				The patient was investigated extensively with blood tests, cultures, X-rays and CT scans with no identified focus of infection.

# Public Case Detail

Cases Count: 393

**Case Number : 244424**

**Data Entry Date :** 08/09/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :** 99U

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Blood creatine phosphokinase increased		Patient experienced increased CK serum.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	550 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Creatine phosphokinase		15/08/2008	895	

# Public Case Detail

Cases Count: 393

**Case Number : 244425**

**Data Entry Date :** 08/09/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 12/08/2008

**Age :**

**DOB :** 31/07/1980

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced neutropenia.	Ceased Clopine

<b>Medicine details :</b>			
CLOPINE (Suspected)	Reason :		
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 03/07/2008	<b>Stopped :</b> 12/08/2008	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		08/08/2008	4.60	
White blood cells		12/08/2008	3.10	
White blood cells		15/08/2008	3.10	
Neutrophils		08/08/2008	1.80	
Neutrophils		12/08/2008	0.80	
Neutrophils		15/08/2008	1.20	

**Case Number : 244453**

**Data Entry Date :** 08/09/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 17/07/2008

**Age :**

**DOB :** 02/04/1968

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Neutropenia		Low neutrophil counts and neutropenia.	Ceased clopine

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
Tablet	600 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 16/03/2007 <b>Stopped :</b> 09/07/2008

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
White blood cells		01/08/2008	4.10	
White blood cells		31/07/2008	2.50	
White blood cells		28/07/2008	5.40	
White blood cells		25/07/2008	2.90	
White blood cells		23/07/2008	4.80	
White blood cells		21/07/2008	3.60	
White blood cells		17/07/2008	2.40	
White blood cells		16/07/2008	3.30	
White blood cells		15/07/2008	3.60	
White blood cells		14/07/2008	5.40	
White blood cells		10/07/2008	4.50	
White blood cells		09/07/2008	4.10	
White blood cells		08/07/2008	5.00	
White blood cells		07/07/2008	3.70	
White blood cells		03/07/2008	4.80	
White blood cells		30/07/2008	4.20	
White blood cells		02/06/2008	6.30	
Neutrophils		01/08/2008	2.00	
Neutrophils		31/07/2008	1.00	
Neutrophils		28/07/2008	1.50	
Neutrophils		25/07/2008	0.90	
Neutrophils		23/07/2008	1.70	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		21/07/2008	1.10	
Neutrophils		17/07/2008	0.90	
Neutrophils		16/07/2008	1.00	
Neutrophils		15/07/2008	1.00	
Neutrophils		14/07/2008	1.50	
Neutrophils		10/07/2008	1.80	
Neutrophils		09/07/2008	1.00	
Neutrophils		08/07/2008	1.90	
Neutrophils		07/07/2008	1.30	
Neutrophils		03/07/2008	1.70	
Neutrophils		30/06/2008	1.50	
Neutrophils		02/06/2008	3.10	

# Public Case Detail

Cases Count: 393

**Case Number : 244480**

**Data Entry Date :** 08/09/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/05/2008

**Age :**

**DOB :** 02/09/1932

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** Had previously been on Clozaril with no problems.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased		Blood creatine phosphokinase increased, neutrophil count decreased.	
Neutrophil count decreased			

## Medicine details :

**CLOPINE (Suspected)**

**Reason :**

Tablet

150 Milligram

Daily

Oral

**Batch :**

**Started :**

**Stopped :**

0

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin				Troponin level was 0.3 (unit and normal range not specified) which was reported as normal.
Creatine phosphokinase		15/05/2008	63	Unit & normal range not specified
Creatine phosphokinase		26/07/2008	1257	Unit & normal range not specified
Creatine phosphokinase		28/07/2008	1455	Unit & normal range not specified
Neutrophils				Unit & normal range not specified - 26 - 7.6

## Case Number : 244532

**Data Entry Date :** 10/09/2008

**Gender :** M

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 23/09/1974

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** patient is an IV drug user and has hepatitis C, recently discharged from jail, and had been receiving methadone until stopping a week prior to event

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Faecaloma	Caused or prolonged inpatient hospitalisation	Distended abdomen, faecal impaction, acidosis, tachycardia, suspected overdose and collapsed state.	
Tachycardia	Caused or prolonged inpatient hospitalisation	persistent 120 bpm or higher	
Overdose	Caused or prolonged inpatient hospitalisation	suspected clozapine overdose	
Acidosis	Caused or prolonged inpatient hospitalisation		

### Medicine details :

**CLOPINE (Suspected)**

**Reason :** Unspecified schizophrenia

400 Milligram Daily

**Batch :**

**Started :** 20/12/2007

**Stopped :** 04/08/2008

0

# Public Case Detail

Cases Count: 393

**Case Number : 244543**

**Data Entry Date :** 10/09/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 30/01/1982

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Blood creatine phosphokinase increased		Increased creatine kinase levels.	

**Medicine details :**

<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 04/07/2008	<b>Stopped :</b>	

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Creatine kinase MB				Aug - 2008: 625 (>7 times ULN)



# Public Case Detail

Cases Count: 393

**Case Number : 244544**

**Data Entry Date :** 10/09/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 17/07/1974

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Myocarditis	Ceased clopine

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	250 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 29/07/2008	<b>Stopped :</b> 13/08/2008	

# Public Case Detail

Cases Count: 393

**Case Number : 244562**

**Data Entry Date :** 11/09/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 01/03/1942

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Convulsion		Because of poor compliance, the patient had stopped Clozaril on 20 Sep 2001 and restarted at full dose abruptly (about 7 to 9 years ago). The patient experienced seizures by stopping Clozaril and restarting at full dose.	
Treatment noncompliance			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
<b>Batch :</b>	<b>Started :</b> 03/06/1994	<b>Stopped :</b> 20/09/2001	

# Public Case Detail

Cases Count: 393

**Case Number : 244976**

**Data Entry Date :** 30/09/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 31/07/2008

**Age :**

**DOB :** 03/03/1941

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Intestinal obstruction		Functional bowel obstruction secondary to constipation.	
Constipation			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
		375 Milligram	Daily
<b>Batch :</b>	<b>Started :</b> 05/05/2003	<b>Stopped :</b>	31/08/2047

# Public Case Detail

Cases Count: 393

**Case Number : 244984**

**Data Entry Date :** 30/09/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 24/04/1970

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Cardiomyopathy		Cardiomyopathy and reduced ejection fraction	Ceased clopine
Ejection fraction decreased			

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 10/01/2007	<b>Stopped :</b> 17/07/2008	

## Case Number : 245166

Data Entry Date : 03/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/02/2007

Age :

DOB : 24/05/1948

Outcome : 15/02/2007

Causality : Causality possible

Death

Information: Current Condition: Overweight, hypertensive, smoker.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Death	Death	The reporter stated that the patient was deceased and that he had died on 15/02/2007. Follow up received from the coroner on 04/09/2008.	
Arrhythmia	Death		
Drug level increased	Death		
Hyperhidrosis	Death		

### Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	700 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started : 15/02/1996</b>	<b>Stopped :</b>	
<b>SERTRALINE HYDROCHLORIDE (Suspected)</b>		<b>Reason :</b>	
	100 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				Toxicology report revealed high level of clozapine which was capable of being toxic
Serum drug level		19/02/2008	0.5 mg/l	Sertraline level
Serum drug level		19/02/2008	3.9 mg/l	Clozapine level
Serum drug level		19/02/2008	2.9 mg/l	Desmethyl clozapine

# Public Case Detail

Cases Count: 393

**Case Number : 245270**

**Data Entry Date :** 08/10/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 21/08/2008

**Age :**

**DOB :** 22/01/1978

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion		30 year old male patient experienced a tonic-clonic seizure whilst on Clopine.	He was given midazolam 5 mg intravenous stat and was reviewed by the neurologist. Treatment with Clopine is continuing and he is having a variable dose of lamotrigine.

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
Tablet	75 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 15/08/2008 <b>Stopped :</b>
<b>ZUCLOPENTHIXOL ACETATE (Suspected)</b>	<b>Reason :</b> Unspecified psychosis
	100 Milligram Daily
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

## Case Number : 245272

**Data Entry Date :** 08/10/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 15/08/2008  
**Outcome :**  
 Not yet recovered

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 10/06/1960  
**Causality :** Causality probable

### Information:

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis	Caused or prolonged inpatient hospitalisation	A 48 year old male who ceased Clopine treatment due to experience clozapine induced myocarditis.	Transferred to CCU. Ceased Clopine. Aspirin, Plavix, Metoprolol and Ramipril.
Pyrexia	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	125 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>DOCUSATE SODIUM (Other drug)</b>		<b>Reason :</b> Constipation	
	120 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Troponin				1.03
White blood cells				12.6 x 10 <sup>9</sup> /L
C-Reactive Protein				186
Chest X-ray				Normal
Electrocardiography				Showed generalised ST elevation and T-wave flattening
Echocardiogram				Showed new mild impairment of left ventricular (LV) function (LVEF ~40%, which was previously normal), with inferior and inferioseptal wall akinesia of LV.

## Case Number : 245359

**Data Entry Date :** 13/10/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 15/08/2008  
**Outcome :** 28/08/2008  
 Recovered

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 04/11/1962  
**Causality :** Causality possible

### Information:

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis	Caused or prolonged inpatient hospitalisation	Experienced possible myocarditis, elevated troponin I, urticarial rash and chest pain.	Ceased Clopine
Chest pain	Caused or prolonged inpatient hospitalisation		
Troponin I increased	Caused or prolonged inpatient hospitalisation		
Urticaria	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
	50 Milligram	Daily	Oral
<b>Batch :</b> 25820/26305	<b>Started :</b> 13/08/2008	<b>Stopped :</b> 27/08/2008	
<b>SODIUM VALPROATE (Other drug)</b>		<b>Reason :</b>	
	2000 Milligram	Daily	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>VITAMIN NOS (Other drug)</b>		<b>Reason :</b>	
	1 Dose Unspec	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Troponin		26/08/2008	0.20 NG/ML	
Troponin		27/08/2008	0.03 NG/ML	
Troponin		28/08/2008	0.02 NG/ML	
Creatine kinase MB		27/08/2008	68	
Creatine kinase MB		28/08/2008	32	
Serum drug level		26/08/2008	66 Microg/L	



## Case Number : 245364

Data Entry Date : 13/10/2008

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 104

Onset Date : 26/08/2008

Age :

DOB : 04/11/1962

Outcome :

Causality : Causality probable

Recovered

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Chest pain	Caused or prolonged inpatient hospitalisation	Chest pain and urticarial rash	Ceased Clopine, monitored with blood tests
Urticaria	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

CLOPINE (Suspected)

Reason : Unspecified schizophrenia

75 Milligram Daily

Batch :

Started : 13/08/2008

Stopped : 27/08/2008

FISH OIL NOS (Other drug)

Reason :

Batch :

Started :

Stopped :

MULTIVITAMINS (Other drug)

Reason :

Batch :

Started :

Stopped :

SODIUM VALPROATE (Other drug)

Reason :

2 Gram Daily

Batch :

Started :

Stopped :

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin		26/08/2008	0.20	
Troponin		27/08/2008	0.03	
Troponin		28/08/2008	0.02	
Creatinine		27/08/2008	68	
Creatinine		28/08/2008	32	
Serum drug level		26/08/2008	66	

# Public Case Detail

Cases Count: 393

**Case Number : 245370**

**Data Entry Date :** 13/10/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 24/07/2008  
**Outcome :** 25/07/2008  
 Recovered

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 31/10/1944  
**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Atrial fibrillation	Caused or prolonged inpatient hospitalisation	Patient experienced cardiac complications.	Ceased Clopine
Syncope	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
	450 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 245399**

**Data Entry Date :** 14/10/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/08/2008

**Age :**

**DOB :** 31/10/1960

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Pneumonia		Pneumonia	Ceased Clopine

**Medicine details :**

<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	900 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	L TERM	<b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 245401**

**Data Entry Date :** 14/10/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 07/05/1965

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Cardiomyopathy		Patient experienced cardiomyopathy.	Ceased Clopine

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	700 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 245402**

**Data Entry Date :** 14/10/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/07/2008

**Age :**

**DOB :** 13/02/1947

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Syncope	Caused or prolonged inpatient hospitalisation	Patient experienced a fall and fractured her right arm, patient also has a history of lithium toxicity	Ceased Clopine
Therapeutic agent toxicity	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 01/01/2002	<b>Stopped :</b> 22/07/2008	
<b>LITHIUM CARBONATE (Suspected)</b>		<b>Reason :</b> Depression	
Tablet	500 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>DOTHIEPIN HYDROCHLORIDE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Serum drug level				Lithium blood level: mildly toxic.

## Case Number : 245405

Data Entry Date : 14/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 19/08/2008

Age :

DOB : 22/04/1952

Outcome :

Causality : Causality possible

Recovered

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Patient experienced clozapine-induced myocarditis.	Clopine was ceased, dose of ramipril was increased and bisoprolol was started.

#### Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	300 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 30/07/2008 <b>Stopped :</b> 19/08/2008
<b>ASPIRIN (Other drug)</b>	<b>Reason :</b>
Tablet	100 Milligram Oral
<b>Batch :</b>	<b>Started :</b> 26/06/2008 <b>Stopped :</b>
<b>RAMIPRIL (Other drug)</b>	<b>Reason :</b>
	1.3 Milligram Daily
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>ZUCLOPENTHIXOL ACETATE (Other drug)</b>	<b>Reason :</b> Unspecified psychosis
	20 Milligram Daily
<b>Batch :</b>	<b>Started :</b> 05/06/2008 <b>Stopped :</b>

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin		05/08/2008	0.00	
Troponin		06/08/2008	0.02	
Troponin		12/08/2008	0.00	
Troponin		19/08/2008	0.40	
Troponin		19/08/2008	0.04	
Troponin		20/08/2008	0.00	
Biochemistry				Pre-clozapine:LVEF-35% (known LV impairment prior to clozapine).
Heart Rate				Aug-2008: Heart rate-mild tachycardia of 104 BPM.
Electrocardiography				Aug-2008: ECG-Generalised T-Wave flattening and upward sloping of ST segment.

# Public Case Detail

Cases Count: 393

## Case Number : 245413

Data Entry Date : 14/10/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/08/2008

Age :

DOB : 26/12/1958

Outcome :

Causality : Causality possible

Unknown

**Information:** Request for additional information has been faxed to the patient's treating doctor.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Cardiac arrest		Patient commenced treatment with clozapine and switched to the Clopine brand on 19/7/2004. Patient experienced a cardiac arrest.	Ceased Clopine

### Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 19/07/2004	<b>Stopped :</b>	17/08/2008

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells				Normal
Neutrophils				Normal

## Case Number : 245437

Data Entry Date : 14/10/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 01/09/2008

Age :

DOB : 07/05/1959

Outcome :

Causality : Causality possible

Not yet recovered

### Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Dysarthria		Patient ceased treatment with Clopine due to slurred speech, tachycardia, throat tightness, excess drooling, being dizzy, abnormal ECG (V1 and V2 T-wave inversion), and elevated creatine kinase.	Ceased Clopine.
Blood creatine phosphokinase increased			
Dizziness			
Drooling			
Electrocardiogram T wave inversion			
Electrocardiogram abnormal			
Tachycardia			
Throat tightness			

### Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
250 Milligram Daily Oral	
<b>Batch :</b>	<b>Started :</b> 18/08/2008 <b>Stopped :</b> 02/09/2008
<b>BECLOMETHASONE DIPROPIONATE (Other drug)</b>	<b>Reason :</b>
200 Microgram	
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>DOCUSATE SODIUM (Other drug)</b>	<b>Reason :</b>
Tablet 2 Dose Unspec	
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>
<b>SALBUTAMOL (Other drug)</b>	<b>Reason :</b> Asthma
Inhalation	
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography		01/09/2008	V1 and V2 T-Wave inversion	



**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Troponin		01/09/2008	0.05	
Creatine kinase MB		01/09/2008	852	
Haemoglobin		01/09/2008	112	

# Public Case Detail

Cases Count: 393

**Case Number : 245439**

**Data Entry Date :** 14/10/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 17/09/2008  
**Outcome :**  
 Recovered

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 01/03/1974  
**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Neuroleptic malignant syndrome	Caused or prolonged inpatient hospitalisation	Patient developed fever, and later in the day had a grand mal seizure. Patient had also developed Neuroleptic malignant syndrome on an unknown date and symptoms of fever and cardiovascular instability persisted for some days and creatine kinase peaked at 13000	Ceased ziprasidone. Treated with bromocriptine
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation		
Cardiovascular insufficiency	Caused or prolonged inpatient hospitalisation		
Grand mal convulsion	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>Lexapro (Suspected)</b>		<b>Reason : Depression</b>	
	10 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started : 30/03/2008</b>	<b>Stopped :</b>	
<b>PERIACTIN (Suspected)</b>		<b>Reason :</b>	
	4 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>Zeldox (Suspected)</b>		<b>Reason : Unspecified schizophrenia</b>	
Capsule	160 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started : 17/07/2008</b>	<b>Stopped :</b>	0

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Creatine phosphokinase	<200	29/09/2008	13000	
Creatine phosphokinase	<200	22/09/2008	4000	
Creatine phosphokinase	<200	29/09/2008	164	

# Public Case Detail

Cases Count: 393

**Case Number : 245539**

**Data Entry Date :** 16/10/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/05/2008

**Age :**

**DOB :** 18/03/1983

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Hirsutism		Patient has noticed an increase in facial hair growth and has gained alot of weight, about 10 to 20kg.	Sodium valproate discontinued for a year.
Weight increased			

**Medicine details :**

<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	450 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	L TERM	<b>Stopped :</b> Continuing.
<b>SODIUM VALPROATE (Suspected)</b>		<b>Reason :</b> Manic-depression psycho,manic	
Tablet	1 Gram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/04/2008	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 245580**

**Data Entry Date :** 20/10/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 27/08/2008

**Age :**

**DOB :** 26/02/1971

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Hypotension		Patient experienced severe hypotension.	Clozaril ceased.

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	25 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 13/08/2008	<b>Stopped :</b>	27/08/2008

## Case Number : 245583

Data Entry Date : 20/10/2008

Gender : M

Hospitalisation : Admitted to hospital

Weight (kg) : 0

Onset Date : 25/06/2008

Age :

DOB : 10/01/1974

Outcome :

Causality : Causality possible

Recovered

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Heaviness in chest, elevated creatine kinase, shortness of breath and palpitations.	
Blood creatine phosphokinase increased	Caused or prolonged inpatient hospitalisation		
Chest discomfort	Caused or prolonged inpatient hospitalisation		
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Haematocrit decreased	Caused or prolonged inpatient hospitalisation		
Lymphocyte count decreased	Caused or prolonged inpatient hospitalisation		
Palpitations	Caused or prolonged inpatient hospitalisation		
Red blood cell count decreased	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

##### CLOZARIL (Suspected)

Reason :

Tablet 325 Milligram Daily Oral

Batch : Started : 03/06/2008 Stopped :

##### ANTIDEPRESSANT NOS (Other drug)

Reason :

Batch : Started : Stopped :

##### EFEXOR-XR (Other drug)

Reason :

300 Milligram

Batch : Started : Stopped :

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		25/06/2008	266 IU/l	
Creatine phosphokinase		01/09/2008	970 IU/l	
Creatine phosphokinase		02/09/2008	622 IU/l	
Creatine phosphokinase		02/09/2008	626 IU/l	
Creatine phosphokinase		04/09/2008	355	
Creatine phosphokinase		05/09/2008	335	
Haematocrit		01/09/2008	0.39 L/L	
Lymphocytes		25/06/2008	0.4 x 10 <sup>9</sup> /L	
Red blood cells		25/06/2008	4.31 x 10 <sup>12</sup> /L	
Red blood cells		01/09/2008	4.24 x 10 <sup>12</sup> /L	
Echocardiogram				04/09/2008: Trivial circumferential pericardial effusion.

# Public Case Detail

Cases Count: 393

**Case Number : 245631**

**Data Entry Date :** 20/10/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 31/08/2008

**Age :**

**DOB :** 01/06/1962

**Outcome :**

**Causality :** Causality probable

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	unwell, tiredness, lethargy, poor appetite and diarrhoea, increased temperature	ceased clopine

**Medicine details :**

<b>CLOZAPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia	
200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>
<b>ATORVASTATIN (Other drug)</b>	<b>Reason :</b>	
20 Milligram		Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>
<b>FLUOXETINE HYDROCHLORIDE (Other drug)</b>	<b>Reason :</b>	
20 Milligram		Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>
<b>PANTOPRAZOLE (Other drug)</b>	<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Haematology				elevated Tropin I, creatine kinase, white blood cells, neutrophils and eosinophils.



# Public Case Detail

Cases Count: 393

**Case Number : 245640**

**Data Entry Date :** 20/10/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 25/04/1973

**Outcome :**

**Causality :** Causality probable

Unknown

**Information:** Patient commenced treatment with Clopine and was stable on 550mg po daily for several years prior to event. Patient was recommenced with Clopine on 11/9/08 and at time of report, did not have a recurrence of neutropenia.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Thrombocytopenia		thrombocytopenia with platelet count of 46. Experienced moderate neutropenia.	Ceased Clopine
Neutropenia			

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>
	50 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 16/03/2005 <b>Stopped :</b> 05/09/2008

# Public Case Detail

Cases Count: 393

**Case Number : 245645**

**Data Entry Date :** 20/10/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 11/09/2008

**Age :**

**DOB :** 25/07/1978

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Neutropenia		severe neutropenia	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 27/09/2006	<b>Stopped :</b> 11/09/2008	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		23/07/2008	5.90	
White blood cells		14/08/2008	4.90	
White blood cells		11/09/2008	3.70	
White blood cells		12/08/2008	4.00	
White blood cells		13/09/2008	4.60	
White blood cells		18/09/2008	4.70	
Neutrophils		23/07/2008	2.70	
Neutrophils		14/08/2008	1.70	
Neutrophils		11/09/2008	0.90	
Neutrophils		12/08/2008	1.50	
Neutrophils		13/09/2008	1.70	
Neutrophils		18/09/2008	1.90	

# Public Case Detail

Cases Count: 393

**Case Number : 245646**

**Data Entry Date :** 20/10/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 19/03/2008

**Age :**

**DOB :** 25/07/1971

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Pericarditis		Pericarditis	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
	125 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 03/03/2008	<b>Stopped :</b> 19/03/2008	0

## Case Number : 245715

**Data Entry Date :** 21/10/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 22/08/2008  
**Outcome :**  
 Unknown

**Gender :** F  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 29/09/1972  
**Causality :** Causality possible

### Information:

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
White blood cell count increased	Caused or prolonged inpatient hospitalisation	Raised white blood cells, eosinophilia, raised neutrophil count, elevated platelets and elevated monocytes.	
Eosinophilia	Caused or prolonged inpatient hospitalisation		
Monocyte count increased	Caused or prolonged inpatient hospitalisation		
Neutrophil count increased	Caused or prolonged inpatient hospitalisation		
Platelet count increased	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia		
	350 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 25/07/2008	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
White blood cells		22/08/2008	16.20 x 10 <sup>9</sup> /L	
White blood cells		15/08/2008	9.60 x 10 <sup>9</sup> /L	
White blood cells		07/08/2008	9.70 x 10 <sup>9</sup> /L	
Neutrophils		22/08/2008	10.80 x 10 <sup>9</sup> /L	
Neutrophils		15/08/2008	6.40 x 10 <sup>9</sup> /L	
Neutrophils		07/08/2008	5.40 x 10 <sup>9</sup> /L	
Eosinophils		22/08/2008	1.3	
Platelets		22/08/2008	473	
Monocytes		22/08/2008	1.3	

# Public Case Detail

Cases Count: 393

**Case Number : 245775**

**Data Entry Date :** 23/10/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/08/2008

**Age :**

**DOB :** 25/03/1976

**Outcome :**

**Causality :** Causality possible

Death

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Intestinal perforation	Death	Patient died due to a perforated bowel whilst being treated with Clopine 400mg.	

**Medicine details :**

<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	L TERM	<b>Stopped :</b>

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Neutrophils				The patient's neutrophil counts were within normal ranges.
White blood cells				Patient's white cell counts were within normal ranges for the treatment period.

# Public Case Detail

Cases Count: 393

**Case Number : 245889**

**Data Entry Date :** 29/10/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 27/09/2008

**Age :**

**DOB :** 29/06/1978

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Arrhythmia		Patient experienced arrhythmia, hypersalivation and tiredness.	
Fatigue			
Salivary hypersecretion			

**Medicine details :**

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>
Tablet	12.5 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 27/08/2008 <b>Stopped :</b> 17/09/2008

# Public Case Detail

Cases Count: 393

**Case Number : 245975**

**Data Entry Date :** 05/11/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 05/04/1983

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Pneumonia		Patient developed pneumonia and QT interval prolonged. Sinus tachycardia and left atrial enlargement.	
Electrocardiogram QT interval			
Left atrial dilatation			
Sinus tachycardia			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
	650 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 24/11/2008	<b>Stopped :</b>	
<b>FLUTICASONE PROPIONATE-SALMETEROL XINAFOATE (Otl</b>		<b>Reason :</b>	
Inhalation			Inhalation
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>LAMOTRIGINE (Other drug)</b>		<b>Reason :</b>	
	200 Milligram		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>VENLAFAXINE HYDROCHLORIDE (Other drug)</b>		<b>Reason :</b>	
	300 Milligram		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Other data				13/09/2008: Prolonged QTC interval (508 MS), sinus tachycardia, left atrial enlargement, non-specific T widespread abnormalities. 23/06/2008: QTC interval 437 MS. 13/12/2007: QTC interval 481 MS.

# Public Case Detail

Cases Count: 393

**Case Number : 245990**

**Data Entry Date :** 05/11/2008

**Gender :** M

**Hospitalisation :** Admitted to hospital

**Weight (kg) :** 0

**Onset Date :** 24/09/2008

**Age :**

**DOB :** 21/10/1987

**Outcome :**

**Causality :** Causality possible

Unknown

## Information:

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Pyrexia	Caused or prolonged inpatient hospitalisation	Patient developed a fever of 39.4c.	Clozaril discontinued.
Neutropenia	Caused or prolonged inpatient hospitalisation		
White blood cell count decreased	Caused or prolonged inpatient hospitalisation		

### Medicine details :

CLOZARIL (Suspected)		Reason :	
Tablet	150 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 14/09/2008	<b>Stopped :</b> 30/09/2008	0

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils	7.7-1.6	30/09/2008	0.90x10 <sup>9</sup> /L	
Neutrophils	7.7-1.6	01/10/2008	3.0x10 <sup>9</sup> /L	
White blood cells	11.0-4.5	30/09/2008	2.80x10 <sup>9</sup> /L	
White blood cells	11.0-4.5	01/10/2008	5.8x10 <sup>9</sup> /L	



# Public Case Detail

Cases Count: 393

**Case Number : 245996**

**Data Entry Date :** 05/11/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 12/09/2008  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 18/03/1983  
**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Troponin increased	Caused or prolonged inpatient hospitalisation	Patient experienced elevated troponin, persistent low grade fever, mild neutrophilia, moderate monocytosis and pharyngitis.	
Monocytosis	Caused or prolonged inpatient hospitalisation		
Neutrophilia	Caused or prolonged inpatient hospitalisation		
Pharyngitis	Caused or prolonged inpatient hospitalisation		
Pyrexia	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	87.5 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 29/08/2008	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Neutrophils	1.8 - 7.7 x 10 <sup>9</sup> /L	17/09/2008	8.7 x 10 <sup>9</sup> /L	
White blood cells	4.5 - 11.0 x 10 <sup>9</sup> /L	17/09/2008	12.10 x 10 <sup>9</sup> /L	

## Case Number : 246001

**Data Entry Date :** 05/11/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 04/04/2008  
**Outcome :**  
 Recovered

**Gender :** F  
**Weight (kg) :** 137  
**Age :**  
**DOB :** 13/12/1978  
**Causality :** Causality possible

### Information:

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Pulmonary embolism	Caused or prolonged inpatient hospitalisation	Patient experienced pain in her leg, pain in her chest and weight gain. Patient collapsed and was taken to hospital, she was found to have a pulmonary embolism.	
Chest pain	Caused or prolonged inpatient hospitalisation		
Cognitive disorder	Caused or prolonged inpatient hospitalisation		
Pain in extremity	Caused or prolonged inpatient hospitalisation		
Weight increased	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
Other data				4/4/08: Scan showed significant emboli.

**Case Number : 246112**

**Data Entry Date :** 10/11/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**Outcome :**

**DOB :** 28/09/1950

Unknown

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Ventricular hypokinesia		The patient with a history of hypertension and smoking, had an echocardiogram which revealed left atrial enlargement, a normal left ventricular size and function but a sigmoid shaped septum and a marked difference in the left ventricular shortening in comparison to the last year's echocardiogram which was not commented upon previously. Prior to this another echocardiogram performed on 10/08/08 noted sinus tachycardia and a atrial right bundle branch block. No such events were reported in echocardiograms performed on 02/08/08 and 21/06/08.	
Bundle branch block right			
Sinus tachycardia			
Tachycardia			

**Medicine details :**

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	600 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b>
<b>Stopped :</b>	
<b>VENLAFAXINE HYDROCHLORIDE (Suspected)</b>	<b>Reason :</b>
	225 Milligram Daily
<b>Batch :</b>	<b>Started :</b>
<b>Stopped :</b>	

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Echocardiogram		21/06/2006	Normal size and function	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram		02/08/2007	Normal left ventricular systolic function, normal valve function	
Echocardiogram		10/08/2008	Sinus tachycardia and partial RBBB	
Echocardiogram		08/10/2008	Marked difference in the left ventricular shortening in comparison to last year echocardiogram. Right ventricular systolic pressure 35mmHg.	



# Public Case Detail

Cases Count: 393

**Case Number : 246184**

**Data Entry Date :** 12/11/2008

**Hospitalisation :**

**Onset Date :**

**Outcome :**

Unknown

**Gender :** M

**Weight (kg) :** 0

**Age :**

**DOB :** 15/10/1965

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Dilatation ventricular		Mildly dilated left ventricle, left ventricular hypertrophy, left atrial dilatation/left atrium enlargement, mildly dilated aortic root.	
Aortic dilatation			
Left atrial dilatation			
Left ventricular hypertrophy			

**Medicine details :**

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>
	1 Dose Unspec Daily
<b>Batch :</b>	<b>Started :</b>
	<b>Stopped :</b>



# Public Case Detail

Cases Count: 393

## Case Number : 246192

Data Entry Date : 12/11/2008

Hospitalisation :

Onset Date : 19/09/2008

Outcome :

Unknown

Gender : M

Weight (kg) : 0

Age :

DOB : 13/02/1970

Causality : Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis		Suspected myocarditis.	Ceased clopine
Cardiac enzymes increased			
Pyrexia			
Tachycardia			

#### Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	500 Milligram Daily Oral
Batch :	Started : 03/09/2008 Stopped : 19/09/2008

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Troponin		27/08/2008	0.02 MCG/L	
Troponin		18/09/2008	0.09 MCG/L	
Troponin		19/09/2008	0.50 MCG/L	
Creatine kinase MB		27/08/2008	538 U/L	
Creatine kinase MB		19/09/2008	1280 U/L	
Other data		21/09/2008	100 beats per minute	

# Public Case Detail

Cases Count: 393

## Case Number : 246313

Data Entry Date : 17/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 20/08/1948

Outcome : 09/10/2008

Causality : Causality possible

Death, maybe drug

**Information:** No past medical history or concomitant medications. Suspected heart attack (myocardial infarction). The patient's white cell and neutrophil counts were within normal ranges for the treatment period. Fatal report.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Death	Death	60 year old male patient who experienced renal issues and arrhythmias and died due to unknown reasons ( suspected heart attack) whilst being treated with Clopine.	
Arrhythmia	Death		
Renal disorder	Death		

### Medicine details :

CLOPINE (Suspected)

Reason :

Tablet

100 Milligram

Daily

Oral

Batch :

Started : 08/07/2008

Stopped : 09/10/2008



## Case Number : 246411

**Data Entry Date :** 19/11/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 15/09/2008  
**Outcome :**  
 Not yet recovered

**Gender :** F  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 30/10/1972  
**Causality :** Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Liver function test abnormal		Stopped smoking and found elevated LFTs, decreased platelet count, clozapine toxicity with elevated clozapine plasma levels, excess sedation	Clopine stopped;
Drug toxicity			
Sedation			
Thrombocytopenia			

#### Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b>			
	650 Milligram	Daily		
<b>Batch :</b>	<b>Started :</b> 30/08/2008	<b>Stopped :</b> 10/10/2008		
<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia			
	800 Milligram	Daily	Oral	
<b>Batch :</b>	<b>Started :</b> 29/04/2008	<b>Stopped :</b> 29/08/2008	0	
<b>AMISULPRIDE (Other drug)</b>	<b>Reason :</b>			
	600 Milligram	Daily		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0	
<b>CITALOPRAM HYDROBROMIDE (Other drug)</b>	<b>Reason :</b>			
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>		
<b>EPILIM (Other drug)</b>	<b>Reason :</b> Unspecified schizophrenia			
	2 Gram	Daily		
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	0	

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Serum drug level		09/10/2008	2.9	Clozapine

# Public Case Detail

Cases Count: 393

**Case Number : 246456**

**Data Entry Date :** 21/11/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 07/10/2008

**Age :**

**DOB :** 02/04/1978

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Neutropenia		Severe neutropenia and moderate leucopenia whilst being treated with Clopine.	Ceased Clopine
Leukopenia			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	550 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 18/06/2008	<b>Stopped :</b> 07/10/2008	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
White blood cells		30/09/2008	3.60	
White blood cells		07/10/2008	2.30	
Neutrophils		30/09/2008	2.20	
Neutrophils		07/10/2008	0.80	

# Public Case Detail

Cases Count: 393

**Case Number : 246546**

**Data Entry Date :** 25/11/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :**  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 06/08/1960  
**Causality :** Causality possible

**Information:** The patient's white cell and neutrophil counts were within normal ranges throughout treatment.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Grand mal convulsion	Caused or prolonged inpatient hospitalisation	The case of a 48 year old male who experienced a grand mal seizure and hyponatraemia whilst on Clopine.	
Hyponatraemia	Caused or prolonged inpatient hospitalisation		

## Medicine details :

<b>ATACAND (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	800 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 14/10/2003	L TERM	<b>Stopped :</b>

## Case Number : 246548

Data Entry Date : 25/11/2008

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 17/10/2008

Age :

DOB : 18/09/1944

Outcome :

Causality : Causality possible

Unknown

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Respiratory disorder	Caused or prolonged inpatient hospitalisation	Patient experienced coronary obstructive respiratory disease, pneumonia and tertiary syphilis.	
Tertiary syphilis	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	450 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 30/08/2004	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 246572**

**Data Entry Date :** 25/11/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 26/07/2008

**Age :**

**Outcome :** 26/07/2008

**DOB :** 23/08/1980

Death

**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Depression	Death	Patient overdosed on medications available, led to patient being comatose and could not be resuscitated, patient was hospitalised on 26/07/08, died on the 26/07/08, patient had recently developed some depression symptoms, fluctuating paranoid thoughts while under stress.	
Coma	Death		
Completed suicide	Death		
Intentional overdose	Death		
Paranoia	Death		
Stress	Death		

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 12/04/2000	<b>Stopped :</b>	
<b>QUETIAPINE (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>SERTRALINE HYDROCHLORIDE (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b> 22/04/2008	<b>Stopped :</b>	

## Case Number : 246590

Data Entry Date : 25/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

DOB : 08/09/1958

Outcome :

Causality : Causality possible

Unknown

**Information:** History: psychosis, hypothyroidism, TSH decreased, hypertension and affective disorder.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Blood potassium		Blood potassium increased, left ventricular hypertrophy, echocardiogram abnormal, drug level above therapeutic and blood thyroid stimulating hormone decreased.	
Blood thyroid stimulating hormone decreased			
Drug level above therapeutic			
Echocardiogram abnormal			
Left ventricular hypertrophy			

### Medicine details :

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>
625 Milligram Daily	
<b>Batch :</b>	<b>Started :</b>
<b>Stopped :</b>	
<b>LITHIUM CARBONATE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> 19/08/2008
<b>Stopped :</b>	
<b>SODIUM VALPROATE (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b>
<b>Stopped :</b>	
<b>THYROXINE SODIUM (Other drug)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b>
<b>Stopped :</b>	

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Blood culture	5.3 - 3.7	25/08/2008	5.5	Blood potassium high:
Echocardiogram				26/09/08: Significant mild concentric left ventricular hypertrophy.

# Public Case Detail

Cases Count: 393

**Case Number : 246591**

**Data Entry Date :** 25/11/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 21/10/2008  
**Outcome :**  
 Unknown

**Gender :** F  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 23/06/1947  
**Causality :** Causality possible

**Information:** Concurrent condition of chronic paranoid schizophrenia.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Convulsion	Caused or prolonged inpatient hospitalisation	Patient experienced a possible seizure.	Treated with Epilim

## Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	650 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/05/1957	L TERM	<b>Stopped :</b>

# Public Case Detail

Cases Count: 393

**Case Number : 246649**

**Data Entry Date :** 26/11/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/09/2008

**Age :**

**DOB :** 20/09/1975

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** The patient has a past medical history on ECG of sinus rythym (30/03/06), sinus tachycardia (118 bpm) and QTc interval of 511 msec (06/07/06), and sinus tachycardia of 118 bpm and a t-wave inversion infero-laterally (consider ischaemia) (16/07/06). Previous echocardiograms were generally normal (30/06/06, 08/03/07 and 10/10/07).

## Reaction :

Preferred Term	Severity	Report Description	Treatment
ECG signs of myocardial ischaemia			

## Medicine details :

CLOPINE (Suspected)	Reason :
Tablet	550 Milligram Daily Oral
Batch :	Started : 24/05/2006 Stopped :

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Electrocardiography		30/03/2006	Sinus rythym, otherwise normal	
Electrocardiography		05/04/2006	QTc Interval = 383 msec	
Electrocardiography		23/06/2006	QTc Interval = 504 msec, Sinus Tachycardia (118 BPM)	
Electrocardiography		06/07/2006	QTc Interval = 511 msec, Sinus Tachycardia (120 BPM)	
Electrocardiography		16/07/2006	QTc Interval = 502 msec, Sinus Tachycardia (118 BPM), T-Wave inversion infero-laterally (possibly ischaemia)	
Electrocardiography		10/10/2007	QTc Interval = 406 msec	
Electrocardiography		15/09/2008	QTc Interval = 435 msec, Sinus Rythym (93 BPM), Possible Inferior Infarct, age undeterminant	
Echocardiogram		30/06/2006	Normal Study	



## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Echocardiogram		15/09/2008	Elevated sinus rate (87-93 BPM), Normal LV size and systolic function, Estimated ejection fraction of 65%, Normal Valvular function.	

## Case Number : 246665

Data Entry Date : 27/11/2008

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date : 15/09/2008

Age :

DOB : 11/11/1982

Outcome : 10/08/2008

Causality : Causality possible

Recovered

**Information:** Patient's white blood cell counts and neutrophil counts were within normal ranges for the treatment period.

### Reaction :

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Life threatening	Patient developed early myocarditis, palpitations, shortness of breath, dizziness, chest tightness and significant postural drops.	Clopine was ceased.
Blood creatine phosphokinase increased	Life threatening		
Blood pressure orthostatic decreased	Life threatening		
Chest discomfort	Life threatening		
Dizziness	Life threatening		
Dyspnoea	Life threatening		
Myocarditis	Life threatening		
Palpitations	Life threatening		

### Medicine details :

<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	375 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 16/08/2008	<b>Stopped :</b> 03/10/2008	

### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Creatine phosphokinase		15/09/2008	11168	
Echocardiogram				Echocardiogram showed mild left ventricular/right ventricular dysfunction and left ventricular ejection fraction of 50%.
Troponin				09/08 Troponin 1 Normal

# Public Case Detail

Cases Count: 393

**Case Number : 246812**

**Data Entry Date :** 04/12/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 30/10/1972

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Drug level increased		Patient experienced liver function tests and increased clozapine levels.	Clopine ceased.
Hepatic function abnormal			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>			
Tablet	800 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>EPILIM (Suspected)</b>			
<b>Reason :</b>			
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 246822**

**Data Entry Date :** 04/12/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 107

**Onset Date :** 20/07/2008

**Age :**

**DOB :** 14/03/1969

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Neutropenia		Patient experienced neutropenia, white blood cell count decreased, eosinophilia, skin rash.	
Eosinophilia			
Rash			
White blood cell count decreased			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/07/2008	<b>Stopped :</b> 14/10/2008	
<b>QUETIAPINE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>RISPERIDONE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>SODIUM VALPROATE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Neutrophils	1.8 - 7.7	14/10/2008	1.40	
Neutrophils	1.8 - 7.7	14/10/2008	1.50	
Neutrophils	1.8 - 7.7	31/10/2008	2.7	
Neutrophils	1.8 - 7.7	20/11/2008	1.5	
White blood cells	4.5 - 11.0	23/09/2008	-	
White blood cells	4.5 - 11.0	14/10/2008	3.40	
White blood cells	4.5 - 11.0	14/10/2008	3.90	
White blood cells	4.5 - 11.0	20/11/2008	4.30	

## Case Number : 246875

**Data Entry Date :** 08/12/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 15/10/2008  
**Outcome :**  
 Recovered

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 27/05/1961  
**Causality :** Causality possible

### Information:

Reaction :	Severity	Report Description	Treatment
Renal impairment	Caused or prolonged inpatient hospitalisation	Patient who initiated Revlimid on alternate days 1-21, experienced renal impairment, extrapyramidal side effects, myoclonic body movements and suspected drug interaction.	Revlimid was stopped and Clozapine dose ws reduced to 150mg daily.
Drug interaction	Caused or prolonged inpatient hospitalisation		
Extrapyramidal disorder	Caused or prolonged inpatient hospitalisation		
Myoclonus	Caused or prolonged inpatient hospitalisation		

Medicine details :			
<b>CLOZAPINE (Interaction)</b>	<b>Reason :</b>		
	450 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/10/2008	<b>Stopped :</b>	
<b>Revlimid (Interaction)</b>	<b>Reason :</b> Multiple myeloma		
	15 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 30/09/2008	<b>Stopped :</b> 15/10/2008	0

# Public Case Detail

Cases Count: 393

**Case Number : 246876**

**Data Entry Date :** 08/12/2008

**Hospitalisation :**

**Onset Date :** 01/11/2008

**Outcome :**  
Unknown

**Gender :** M

**Weight (kg) :** 0

**Age :**

**DOB :** 25/11/1963

**Causality :** Causality probable

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		The patient experienced myocarditis and eosinophilia.	Ceased clozaril
Eosinophilia			

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>	<b>Reason :</b>		
Tablet	250 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 07/10/2008	<b>Stopped :</b> 01/11/2008	

**Case Number : 246880**

**Data Entry Date :** 08/12/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 74.9

**Onset Date :**

**Age :**

**DOB :** 26/03/1963

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** Patient's history: Patient has a history of alcohol abuse and stopped drinking alcohol for a period of time, but now drinks 1 to 2 drinks every second day (has done so for the last 2 years). The consultant cardiologist at the hospital reviewed the echocardiogram performed on 09/03/08 with the original echocardiogram and thought it looked unchanged, therefore unlikely to be cardiomyopathy. Patient has had consistently elevated blood pressure since first recorded when starting clozapine, and it has been in the vicinity of 140-150/85-100. He has had tachycardia since starting clozapine. His most recent observations were blood pressure 140/94, heart rate 120bpm, weight 74.9kg and BMI 26. He has had tachycardia since starting clozapine.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Echocardiogram abnormal		Patient experienced possible cardiomyopathy, abnormal echo, tachycardia, elevated blood pressure and chest discomfort whilst on Clopine.	Treatment with Clopine was titrated up to a maximum dose of 425mg daily. (100mg mane and 325mg nocte).
Cardiomyopathy			
Hypertension			
Tachycardia			

## Medicine details :

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
	425 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 26/03/2007 <b>Stopped :</b> Continuing.

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		23/09/2008	Normal	
White blood cells		21/10/2008	Normal	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Other data				<p>Just prior to starting clozapine, the patient had normal troponin, UEC and LFT. His ECG showed left axis deviation, with minor St changes. A echocardiogram performed on 11/05/07 was reported as normal (normal left ventricular size and systolic function). On the 12/02/08 the patient has an ECG which showed sinus tachycardia, leftward axis and minor St changes. An echocardiogram performed on 22/02/08 showed normal left ventricular size with normal wall thickness and mild global hypokinesis. Grade I/IV left ventricular diastolic dysfunction, and mild left and right atrial enlargement. On 06/03/08, patient reported discomfort, which was clinically evaluated as unlikely to be cardiogenic. An echocardiogram was performed on 09/03/08 which revealed mild to moderate left ventricular hypertrophy with normal left ventricular function. An echocardiogram performed on 22/03/08 reported changes consistent with cardiomyopathy. An echocardiogram on 09/07/08 showed mildly reduced left ventricular contractility suggesting mild cardiomyopathy, normal left ventricular diastolic filling pressure and no significant functional valvular abnormalities. An ECG on 29/07/08, once again showed sinus tachycardia and minor ST changes, and also showed QTc prolongation. A recent follow-up echocardiogram was performed on 08/10/08, and was reported as mildly reduced left ventricular contractility, suggesting mild cardiomyopathy.</p>



# Public Case Detail

Cases Count: 393

**Case Number : 246953**

**Data Entry Date :** 09/12/2008  
**Hospitalisation :** Admitted to hospital  
**Onset Date :**  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 25/11/1979  
**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Gastroenteritis	Caused or prolonged inpatient hospitalisation	Experienced severe gastro whilst being treated with Clopine.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
	150 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 22/10/2008	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 247197**

**Data Entry Date :** 16/12/2008

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 31/10/2008

**Age :**

**DOB :** 23/08/1982

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Neutropenia		Patient experienced severe neutropenia and moderate leucopenia.	Clopine ceased
Leukopenia			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	600 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 11/03/2008	<b>Stopped :</b> 31/10/2008	

<b>Laboratory Investigations :</b>				
<b>Type</b>	<b>Range</b>	<b>Date Tested</b>	<b>Result</b>	<b>Details</b>
White blood cells		05/11/2008	13.00	x 10 <sup>9</sup> /L
White blood cells		02/11/2008	3.30	x 10 <sup>9</sup> /L
White blood cells		01/11/2008	4.00	x 10 <sup>9</sup> /L
White blood cells		31/10/2008	2.70	x 10 <sup>9</sup> /L
White blood cells		30/10/2008	5.10	x 10 <sup>9</sup> /L
Neutrophils		05/11/2008	9.30	x 10 <sup>9</sup> /L
Neutrophils		02/11/2008	0.70	x 10 <sup>9</sup> /L
Neutrophils		01/11/2008	1.60	x 10 <sup>9</sup> /L
Neutrophils		31/10/2008	0.80	x 10 <sup>9</sup> /L
Neutrophils		30/10/2008	3.00	x 10 <sup>9</sup> /L

# Public Case Detail

Cases Count: 393

**Case Number : 247198**

**Data Entry Date :** 16/12/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 17/04/1986

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Drug level decreased		Switched from Clopine tablet to Clopine suspension and experienced reduced clozapine plasma levels.	

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified psychosis	
	900 Milligram		Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
Serum drug level		22/05/2006	299 - 116 - 500mg - Clopine Tabs	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		04/09/2006	363 - 138 - 550mg - Clopine Tabs	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		08/02/2007	328 - 108 - 550mg - Clopine Tabs	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		21/04/2008	147 - 82 - 400mg - Macquarie Suspension	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		11/08/2008	186 - 92 - 400mg - Macquarie Suspension	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		25/08/2008	324 - 131 - 700mg - Macquarie Suspension	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		11/09/2008	480 - 160 - 850mg - Macquarie Suspension	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		29/09/2008	268 - 111 - 900mg - Clopine Suspension	Clozapine - Nor-Clozapine - Dose - Form
Serum drug level		05/11/2008	588 - 206 - 900mg - Clopine Tabs	Clozapine - Nor-Clozapine - Dose - Form

# Public Case Detail

Cases Count: 393

**Case Number : 247199**

**Data Entry Date :** 16/12/2008

**Gender :** U

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/10/2008

**Age :** 99u

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Drug level decreased		Patient who was switched from Clopine tablets to Clopine suspension and experienced reduced clozapine plasma levels.	

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified psychosis
<b>Batch :</b>	<b>Started :</b> 600 Milligram Daily Oral
	<b>Stopped :</b>

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Serum drug level		17/09/2008	415 - 600mg - Clopine Tabs	Clozapine - Dose - Form
Serum drug level		01/10/2008	278 - 650mg - Clopine Tabs	Clozapine - Dose - Form
Serum drug level		15/10/2008	235 - 700mg - Clopine suspension	Clozapine - Dose - Form

# Public Case Detail

Cases Count: 393

**Case Number : 247210**

**Data Entry Date :** 17/12/2008

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 28/01/1974

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Left ventricular dysfunction		Left ventricular dysfunction, ejection fraction decreased, lymphocytosis, neutrophilia, neuroleptic malignant syndrome, sinus tachycardia, hypertension, blood cholesterol increased, blood triglycerides increased. Blood glucose increased, treatment noncompliance.	
Blood cholesterol increased			
Blood glucose increased			
Blood triglycerides increased			
Ejection fraction decreased			
Hypertension			
Lymphocytosis			
Neuroleptic malignant syndrome			
Neutrophilia			
Sinus tachycardia			
Treatment noncompliance			

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	600 Milligram Daily Oral
<b>Batch :</b>	<b>Started :</b> 15/02/2008 <b>Stopped :</b> 15/10/2008
<b>SEROQUEL (Suspected)</b>	<b>Reason :</b>
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Cholesterol				Blood cholesterol high 7.1.
Serum glucose				Blood glucose high 5.7

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Blood pressure				140/90 Usal blood pressure.
Triglyceride				High 6.8
Echocardiogram				29/03/2005 Low normal LV contraction with impaired relaxation. 02/06/2008 Mild global LV systolic dysfunction.
Heart Rate				115 high Patient normal ranged 88bpm-112bpm.

# Public Case Detail

Cases Count: 393

**Case Number : 247239**

**Data Entry Date :** 18/12/2008

**Gender :** U

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/10/2008

**Age :** 99u

**Outcome :**

**DOB :**

Unknown

**Causality :** Causality possible

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Drug level decreased		Switched from Clopine tablets to Clopine suspension and experienced reduced clozapine plasma levels.	

**Medicine details :**

<b>CLOPINE (Suspected)</b>	<b>Reason :</b> Unspecified psychosis
	600 Milligram      Daily      Oral
<b>Batch :</b>	<b>Started :</b> <b>Stopped :</b>

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Serum drug level		28/05/2008	392; 600mg; Clopine Tabs	Clopine Plasma Levels, Dose, Form
Serum drug level		17/09/2008	820; 700mg; Macquarie Suspension	Clopine Plasma Levels, Dose, Form
Serum drug level		15/10/2008	362; 700mg; Clopine Suspension	Clopine Plasma Levels, Dose, Form

## Case Number : 247457

**Data Entry Date :** 05/01/2009  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 08/10/2008  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 05/09/1985  
**Causality :** Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Overdose	Caused or prolonged inpatient hospitalisation	Presented with an overdose and experienced tachycardia, shortness of breath and postural hypotension.	
Dyspnoea	Caused or prolonged inpatient hospitalisation		
Orthostatic hypotension	Caused or prolonged inpatient hospitalisation		
Tachycardia	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

<b>CLOZARIL (Suspected)</b>		<b>Reason :</b>	
Tablet	100 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 26/04/2007	<b>Stopped :</b> 21/09/2008	0



## Case Number : 247513

Data Entry Date : 07/01/2009

Gender : F

Hospitalisation :

Weight (kg) : 0

Onset Date : 08/10/2008

Age :

DOB : 20/03/1967

Outcome :

Causality : Causality possible

Not yet recovered

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Leukopenia		Patient experienced severe neutropenia and moderate leucopenia whilst being treated with Clopine and chemotherapy.	
Agranulocytosis			

#### Medicine details :

Chemotherapy NOS (Suspected)

Reason :

Batch :

Started :

Stopped :

CLOPINE (Suspected)

Reason :

Tablet

450 Milligram

Daily

Oral

Batch :

Started : 15/05/2002

Stopped :

#### Laboratory Investigations :

Type	Range	Date Tested	Result	Details
White blood cells		08/10/2008	2.10	
White blood cells		09/10/2008	2.10	
White blood cells		10/10/2008	2.20	
White blood cells		11/10/2008	2.40	
White blood cells		12/10/2008	2.40	
White blood cells		13/10/2008	3.10	
Neutrophils		08/10/2008	0.20	
Neutrophils		09/10/2008	0.10	
Neutrophils		10/10/2008	0.20	
Neutrophils		11/10/2008	0.30	
Neutrophils		12/10/2008	0.40	
Neutrophils		13/10/2008	0.20	

## Case Number : 247515

Data Entry Date : 07/01/2009

Gender : M

Hospitalisation :

Weight (kg) : 0

Onset Date :

Age :

Outcome :

DOB : 30/10/1972

Unknown

Causality : Causality possible

### Information:

#### Reaction :

Preferred Term	Severity	Report Description	Treatment
Antipsychotic drug level increased	Caused or prolonged inpatient hospitalisation	Patient experienced elevated LFT's and clozapine plasma levels.	Ceased Clopine
Hepatic function abnormal	Caused or prolonged inpatient hospitalisation		

#### Medicine details :

<b>CITALOPRAM HYDROBROMIDE (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>CLOPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	800 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>EPILIM (Suspected)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 247563**

**Data Entry Date :** 09/01/2009

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/09/2008

**Age :**

**DOB :** 31/05/1977

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Drug eruption	Caused or prolonged inpatient hospitalisation	Patient experienced skin eruptions (ecrematous plaques on trunk, limbs and face, severe generalised purpuric rash with associated eosinophilial	Clopine ceased
Eosinophilia	Caused or prolonged inpatient hospitalisation		
Purpura	Caused or prolonged inpatient hospitalisation		

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>			
Tablet	200 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 15/09/2008	<b>Stopped :</b> 27/09/2008	
<b>RISPERIDONE (Other drug)</b>			
<b>Reason :</b> Unspecified schizophrenia			
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>SODIUM VALPROATE (Other drug)</b>			
<b>Reason :</b> Unspecified schizophrenia			
	1 Gram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 247612**

**Data Entry Date :** 12/01/2009

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 19/11/2008

**Age :**

**DOB :** 15/08/1985

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

**Reaction :**

Preferred Term	Severity	Report Description	Treatment
Myocarditis	Caused or prolonged inpatient hospitalisation	Clozapine induced myocarditis. Developed tachycardia, troponin rise, diarrhoea, postural hypotension, sweating, pale and lethargic. ECG flattened T waves.	

**Medicine details :**

<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	125 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 30/10/2008	<b>Stopped :</b> 19/11/2008	

# Public Case Detail

Cases Count: 393

**Case Number : 247640**

**Data Entry Date :** 12/01/2009

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 31/10/2008

**Age :**

**DOB :** 03/05/1973

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis		Myocarditis.	Clozapine ceased. Peridopril commenced and changed to risperidone.

<b>Medicine details :</b>			
<b>CLOZAPINE (Suspected)</b>		<b>Reason :</b>	
Tablet	325 Milligram	1 time	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 247705**

**Data Entry Date :** 14/01/2009

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 17/10/2008

**Age :**

**DOB :** 16/03/1949

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Leukopenia		Patient experienced severe neutropenia and severe leucopenia whilst being treated with Clopine.	Clopine ceased.
Agranulocytosis			

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>	<b>Reason :</b>		
Tablet	400 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 12/08/2008	<b>Stopped :</b> 17/10/2008	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		22/10/2008	0.83	
White blood cells		21/10/2008	0.79	
White blood cells		20/10/2008	1.00	
White blood cells		19/10/2008	1.15	
White blood cells		18/10/2008	1.84	
White blood cells		17/10/2008	1.85	
White blood cells		13/10/2008	3.30	
White blood cells		07/10/2008	4.29	
Neutrophils		22/10/2008	0.01	
Neutrophils		21/10/2008	0.01	
Neutrophils		20/10/2008	0.07	
Neutrophils		19/10/2008	0.32	
Neutrophils		18/10/2008	0.50	

**Laboratory Investigations :**

Type	Range	Date Tested	Result	Details
Neutrophils		17/10/2008	0.71	
Neutrophils		13/10/2008	1.60	
Neutrophils		07/10/2008	2.53	

# Public Case Detail

Cases Count: 393

**Case Number : 247706**

**Data Entry Date :** 14/01/2009

**Gender :** F

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 16/10/2008

**Age :**

**DOB :** 06/11/1980

**Outcome :** 22/10/2008

**Causality :** Causality possible

Recovered

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced severe neutropenia and moderate leucopenia whilst being treated with Clopine.	Clopine ceased.
Leukopenia			

<b>Medicine details :</b>			
CLOPINE (Suspected)	Reason :		
Tablet	300 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 21/12/2006	L TERM	<b>Stopped :</b> 16/10/2008

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		22/10/2008	3.30	
White blood cells		21/10/2008	2.40	
White blood cells		20/10/2008	2.30	
White blood cells		19/10/2008	2.40	
White blood cells		18/10/2008	2.10	
White blood cells		17/10/2008	2.40	
White blood cells		16/10/2008	2.20	
White blood cells		14/10/2008	3.50	
White blood cells		15/09/2008	5.00	
Neutrophils		22/10/2008	1.60	
Neutrophils		21/10/2008	0.80	
Neutrophils		20/10/2008	0.50	
Neutrophils		19/10/2008	0.90	
Neutrophils		18/10/2008	1.10	



## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		17/10/2008	0.70	
Neutrophils		16/10/2008	1.00	
Neutrophils		14/10/2008	1.50	
Neutrophils		15/09/2008	2.60	

# Public Case Detail

Cases Count: 393

**Case Number : 247707**

**Data Entry Date :** 14/01/2009  
**Hospitalisation :** Admitted to hospital  
**Onset Date :** 10/10/2008  
**Outcome :**  
 Unknown

**Gender :** M  
**Weight (kg) :** 0  
**Age :**  
**DOB :** 28/11/1991  
**Causality :** Causality possible

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Myocarditis	Caused or prolonged inpatient hospitalisation	Patient developed drug induced myocarditis and cardiac complication myocarditis.	Clozaril discontinued.

<b>Medicine details :</b>			
<b>CLOZARIL (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	275 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b> 25/09/2008	<b>Stopped :</b> 10/10/2008	

# Public Case Detail

Cases Count: 393

**Case Number : 247890**

**Data Entry Date :** 21/01/2009

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :**

**Age :**

**DOB :** 09/10/1971

**Outcome :**

**Causality :** Causality possible

Unknown

**Information:** History of schizophrenia, depression and obesity. Hepatic steatosis, gastro-oesophageal reflux (medically significant) assessed as unlisted according to Core Data Sheet.

## Reaction :

Preferred Term	Severity	Report Description	Treatment
Left atrial dilatation		Patient experienced impaired glucose tolerance which was presently normal. Patient also had fatty liver changes on liver function tests and gastro-oesophageal reflux and obesity.	
Blood cholesterol increased			
Gastrooesophageal reflux disease			
Glucose tolerance impaired			
Hepatic steatosis			
Liver function test abnormal			
Obesity			

## Medicine details :

<b>CLOZARIL (Suspected)</b>	<b>Reason :</b> Unspecified schizophrenia
Tablet	Oral
<b>Batch :</b>	<b>Started :</b> 08/12/2001    L TERM <b>Stopped :</b>

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Liver function tests				The patient also had fatty liver changes on liver function tests and gastro-oesophageal reflux.
Other data				Blood cholesterol high: 6.0 mmol/l, Blood triglycerides high: 3.4
Echocardiogram		27/10/2008	Normal with leftward axis noted.	Echocardiogram: Normal left ventricular size, wall, thickness and systolic function with mild left atrial enlargement.

# Public Case Detail

Cases Count: 393

**Case Number : 247920**

**Data Entry Date :** 22/01/2009

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 15/11/2008

**Age :**

**DOB :** 13/08/1965

**Outcome :**

**Causality :** Causality possible

Recovered

**Information:**

<b>Reaction :</b>			
<b>Preferred Term</b>	<b>Severity</b>	<b>Report Description</b>	<b>Treatment</b>
Pulmonary embolism	Caused or prolonged inpatient hospitalisation	Patient experienced a pulmonary embolism whilst being treated with Clopine.	Ceased fluvoxamine.

<b>Medicine details :</b>			
<b>CLOPINE (Suspected)</b>		<b>Reason :</b> Unspecified schizophrenia	
Tablet	350 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>FLUVOXAMINE MALEATE (Suspected)</b>		<b>Reason :</b>	
	100 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>LITHIUM CARBONATE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	
<b>ZUCLOPENTHIXOL DECANOATE (Other drug)</b>		<b>Reason :</b>	
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

# Public Case Detail

Cases Count: 393

**Case Number : 247923**

**Data Entry Date :** 22/01/2009

**Gender :** M

**Hospitalisation :**

**Weight (kg) :** 0

**Onset Date :** 17/11/2008

**Age :**

**DOB :** 11/07/1958

**Outcome :**

**Causality :** Causality possible

Not yet recovered

**Information:**

<b>Reaction :</b>			
Preferred Term	Severity	Report Description	Treatment
Neutropenia		Patient experienced neutropenia and leucopenia.	Ceased Clopine
Leukopenia			

<b>Medicine details :</b>			
CLOPINE (Suspected)		Reason :	
Tablet	150 Milligram	Daily	Oral
<b>Batch :</b>	<b>Started :</b>	<b>Stopped :</b>	

<b>Laboratory Investigations :</b>				
Type	Range	Date Tested	Result	Details
White blood cells		15/10/2008	4.10	
White blood cells		12/11/2008	2.60	
White blood cells		13/11/2008	2.40	
White blood cells		15/11/2008	2.40	
White blood cells		17/11/2008	2.30	
White blood cells		19/11/2008	3.20	
White blood cells		20/11/2008	3.10	
White blood cells		21/11/2008	2.30	
White blood cells		22/11/2008	2.60	
White blood cells		24/11/2008	2.40	
White blood cells		25/11/2008	3.00	
White blood cells		26/11/2008	3.10	
Neutrophils		15/10/2008	2.40	
Neutrophils		12/11/2008	1.40	
Neutrophils		13/11/2008	1.20	
Neutrophils		15/11/2008	1.00	
Neutrophils		17/11/2008	0.90	
Neutrophils		19/11/2008	1.80	
Neutrophils		20/11/2008	2.00	
Neutrophils		21/11/2008	1.00	
Neutrophils		22/11/2008	1.20	

## Laboratory Investigations :

Type	Range	Date Tested	Result	Details
Neutrophils		24/11/2008	1.20	
Neutrophils		25/11/2008	1.70	
Neutrophils		26/11/2008	1.60	

Selection Parameters : Date Range: 01/08/2007 To 31/12/2059 Unclear causality excluded GM medicines Only Medicine Names: CLOPINE, CLOZAPINE, CLOZARIL